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

MAR 08 2011

Dr. Luiz Carlos de Oliveira
Director, Department of Inspection
for Products of Animal Origin
Ministry of Agriculture and Provisions
Division of International Commerce Control
Ministry of Agriculture Annex
Block D, 4th Floor, Room 436A
70043-900 Brasilia DF, Brazil

Dear Dr. Oliveira:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Brazil's meat inspection system August 31 to September 22, 2010. Comments received from the government of Brazil 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:

Paulo Marcel Armendaris, General Coordinator of Special Programs
Alan Hrapsky, Counselor, US Embassy, Brasilia
Joao Faustino da Silva, Agricultural Specialist, US Embassy, Brasilia
Horrys Friaça - DVM, DSc, Agricultural Attaché, Embassy of Brazil OSTA, FAS
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Country File

FINAL REPORT OF AN AUDIT CONDUCTED IN

BRAZIL

AUGUST 31 THROUGH SEPTEMBER 22, 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 audit report describes the outcome of an on-site audit of Brazil's meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from August 31 through September 22, 2010.

The main focus of the audit was to verify process control as demonstrated by the Central Competent Authority (CCA) - Department of Inspection for Products of Animal Origin (DIPOA) over Brazil's meat inspection system. Special emphases was placed on corrective actions proffered and implemented by the CCA: 1) In response to previous FSIS audits, and 2) In response to Ivermectin violations identified at FSIS port-of-entry (POE) in regard to the current self-suspension of Brazil's eligibility to export beef products to the United States (U.S.).

The audit included the verification of corrective actions taken by the CCA in association with previous audits conducted by FSIS from 2005 through 2009. The auditors' review of CCA documents indicated that the CCA has a system in place that addresses the deficiencies identified in those audits. The review of previous corrective actions indicated that through the documentation, implementation, verification, and the analysis of those corrective actions and preventive measures by the CCA that the CCA has demonstrated ongoing process control.

FSIS import eligibility requirements require that the foreign inspection system be organized and administered by the national government of the foreign country and provide standards equivalent to those of the Federal system of meat and poultry inspection in the U.S. The audit of Brazil's meat inspection system concluded that Brazil was maintaining an inspection system equivalent to the U.S. meat inspection system. However, one systemic noncompliance was identified under the Government Oversight Equivalence Component:

- The CCA was not able to demonstrate National regulatory oversight of the verification of the effectiveness of the product recall system, which consisted of regulations, policies and standard operating procedures. Effective checks were not performed by the CCA to ensure that the recall process was successfully implemented in indentifying, notifying and retrieving the product.

The CCA presented a circular to the FSIS audit team at the exit meeting on September 22, 2010 that stated, "Weekly data will be consolidated by the central level, aiming at verification of the efficiency of procedures for "recall" executed by Brazilian companies. This information will be sent to FSIS to monitor the recall in the United States." However, the CCA did not present a procedural document stating how the recall verification procedures will be implemented or when the procedure will be implemented.

For many years, Brazil's meat industry has operated under the constraints of APHIS regulations in association to foot-and-mouth disease (FMD). In that treatments are typically sufficient to destroy any additional food-borne pathogens present, product safety has relied extensively on the correct application of these processes. During the current audit, it was noted that there were few strategies in place by the CCA to address the adulteration of raw ground beef (or beef components) by *E. coli* O157:H7. Should changes in Brazil's disease status occur permitting export of this product type, it is FSIS' expectation that the CCA develop a control program for *E. coli* O157:H7, which reflects a focus on methods to prevent contamination, the inclusion of government and industry verification testing, and any applicable training of its inspection personnel.

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (the Department of Inspection for Products of Animal Origin (DIPOA)
CCRC	Coordination and control of Residues and Contaminants
CFR	United States Code of Federal Regulations
CGAL	Coordination Office of Laboratory Support
CGPE	International Export and Import Programs Coordination Division
DIPOA	Department of Inspection for Products of Animal Origin
E. coli	*Escherichia coli*
EIAO	Enforcement Investigation Analysis Officer
FMD	Foot and Mouth Disease
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
IAS	International Audit Staff
IPPS	In-Plant Performance System
MAPA	Ministry of Agriculture, Livestock and Supply
MLG	Microbiology Laboratory Guidebook
NOID	Notice of Intent to Delist
OIA	Office of International Affairs
PNCRC	National Plan for the Control of Residues and Contaminents
POE	Port-Of-Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System

RIISPOA	Regulations for the Inspection of Industrial Sanitation for Products of Animal Origin
RTE	Ready-To-Eat
Salmonella	*Salmonella* species
SIF	Brazil's Federal Inspection Service
SSOP	Sanitation Standard Operating Procedures
VIC	Veterinarian-in-Charge

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Brazil's meat food safety system from August 31 through September 22, 2010.

The audit began with an entrance meeting held on August 31, 2010, in Brasilia with the participation of representatives from the Central Competent Authority (CCA) - Department of Inspection for Products of Animal Origin (DIPOA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an ongoing equivalence verification audit with special emphasis on process control verification as demonstrated by the corrective actions implemented by the CCA in response to noncompliances identified during the previous audits from 2005 through 2009.

Additionally, the audit included verification of corrective actions proffered and implemented by the CCA in response to Ivermectin violations identified at FSIS Port-Of-Entry (POE) in regards to Brazil's current self-suspension.

The audit objective was to ensure that Brazil's food safety system governing meat products continues to be equivalent to that of the U.S., with the resultant capacity to produce products, which are safe, unadulterated, and properly labeled.

In pursuit of this objective, FSIS used a risk-based procedure to determine the audit scope, which included an analysis of country performance, production types and volumes, and POE testing results.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA or representatives from the Mato Grosso do Sul, Rio Grande do Sul, Sao Paulo state offices 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 the CCA headquarters, three state offices, four local inspection offices, and two laboratories during which the auditors evaluated the implementation of those management control systems in place, which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A sample of four establishments was selected from a total of 22 establishments certified to export to the U.S. During the establishment visits, particular attention was paid to the

extent to which industry and government interact to control hazards and prevent noncompliances 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, two residue laboratories were audited to verify the CCA's ability to provide adequate technical support to the inspection system.

No microbiology laboratories were audited and were not within the scope of this audit.

Audit Scope Summary

Competent Authority Visits			Locations
Competent Authority	Central Authority	1	Brasilia
	State Offices	3	Mato Grosso do Sul State Office, Campo Grande Rio Grande do Sol State Office, Porto Alegre Sao Paulo State Office, Sao Paulo
Residue Laboratories		2	LANAGRO/Government Residue Laboratory, Campinas, Sao Paulo LANAGRO/Government Residue Laboratory, Porto Alegre, Rio Grande do Sul
Bovine Slaughter/Processing Establishments		3	Bataguassu, Presidente Epitacio and Lins
Beef Processing Establishment		1	Hulha Negras

3. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

The audit standards applied during the review of Brazil'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 under provisions of the Sanitary/Phytosanitary Agreement, which include the following:

- Private laboratories analyze samples for *Salmonella*
- Establishment employees collect the samples for *Salmonella*

- The CCA suspends an establishment from the list of certified establishments after the establishment has failed the third *Salmonella* set

4. BACKGROUND

Brazil is eligible to export fully cooked and fully cooked-shelf stable beef products to the U.S. Prior to their self-suspension, Brazil exported 32,814,488 pounds of meat products to the U.S., between January 1 and June 16, 2010, of which 11,920,536 pounds were reinspected at U.S. POE. A total of 121,116 pounds were rejected, of which no rejections were for food-safety concerns. In addition, 1,950,485 pounds of meat products were rejected due to violative levels of Ivermectin and related compounds.

Since 2005, Brazil has a history of significant noncompliances, enforcement actions culminating with two self-suspensions, which related back to the CCA's lack of government oversight and enforcement control. Summarized below are the results of FSIS audits that were conducted of the Brazilian Food Safety System from 2005 through 2009. FSIS's review of the CCA's corrective actions and preventive measures over this five-year period were to verify that the CCA had maintained ongoing process control and that the previous corrective actions were adequately maintained and effective.

The July/August 2009 FSIS audit did not result in any elevated enforcement actions and did not identify any systemic concerns in the five risk areas: Animal Disease, Sanitation, Slaughter/Processing, Residues and Enforcements (Government Oversight). However, some FSIS requirements were not enforced. There were 11 POE violations detected during fiscal year 2009, which one involved a food safety concern, the other ten were not related to food safety.

The June/July, 2008 FSIS audit resulted in the suspension of Brazil's meat inspection system due to lack of adequate government oversight at the CCA, state, and establishment level. The audit identified noncompliances in Sanitation and HACCP verification components, which resulted in nine enforcement actions: two establishments were delisted and seven establishments received a Notice of Intent to Delist (NOID).

A follow-up audit was conducted August/September 2008 to verify that proffered corrective actions were implemented. The auditors had verified that all previous noncompliances were corrected, new initiatives were implemented, and that process control was achieved. The suspension was lifted as a result of this subsequent audit.

The August/September 2007 FSIS audit did not result in any elevated enforcement actions and did not identify any systemic concerns in the five risk areas: Animal Disease, Sanitation, Slaughter/Processing, Residues and Enforcements (Government Oversight).

The August/September 2006 FSIS audit resulted in an issuance of one NOID and no delistments. The audit identified only isolated noncompliances in Sanitation Standard Operating Procedures (SSOP) and HACCP verification components.

The March/April 2005 FSIS audit was a team enforcement audit due to previous audit results. The audit resulted in 10 of 15 establishments audited receiving NOIDs and another three establishments were delisted. Brazil's ability to export to the U.S. was suspended. The audit identified noncompliances in four of five risk areas: Sanitation, Slaughter/Processing, Residues, and Enforcement (Government Oversight). FSIS conducted three audits, June 2005, July 2005 and October/November 2005, to verify implementation of Brazil's corrective actions. The auditors had verified that all previous noncompliances were corrected and new initiatives were implemented.

The FSIS final audit reports for Brazil'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

As stated earlier, the audit focused on performance within six components upon which system equivalence is based. 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 provide standards equivalent to those of the system of meat and poultry inspection in the U.S. For Brazil, the authority to enforce Brazil's inspection laws are outlined and specified in a Brazil inspection law referred to as Regulations for the Inspection of Industrial Sanitation for Products of Animal Origin (RIISPOA).

The CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Brazilian requirements. Furthermore, these requirements were being consistently applied throughout the system.

FSIS expects that documented periodic supervisory reviews, addressing core components of a foreign country's export eligibility requirements, be performed in all establishments that are eligible for export to the U.S. These reviews serve as a fundamental layer of oversight to ensure that the standards are being met on a routine basis. Bimonthly supervisory reviews were being conducted as intended.

All product recalls in Brazil, which includes all consumer goods, are regulated based on the Consumer Code of Practice, Law N° 8078/90. The law requires the establishment to developing a written recall strategy plan. This involves the notification and coordination of actions when a recall is warranted with government agencies and according to the legislation of the country of import. The country of import includes the U.S.

The establishments audited demonstrated a traceability system for product from the farm through distribution that was integrated with their production chain that enabled the identification of lots or units of products in the event of a recall.

The CCA issued a circular June 4, 2010, prior to the on-site audit, which addressed guidance and responsibilities for inspection and the establishment for the Ivermectin recall. The FSIS Audit Team reviewed 17 Case Files provided by the Veterinarian-In-Charge (VIC), of two establishments audited, one for each container sequestered (retained) by the Federal Inspection Service (SIF) inspection. The Case Files were associated with U.S. POE Ivermectin violative positive product that was returned from the U.S., which resulted in Brazil's self-suspension of exports to the U.S.

The Case Files are similar to FSIS Administrative Enforcement Reports as the Ministry of Agriculture (MAPA) initially starts a case files for all recalled, detained, or retained product and then presents the case file to the local SIF inspection for verification follow-up. The SIF inspection verifies all actions taken as to the movement of product and documents their results within the case file. The case file tracks the systems process movement of the product.

The Audit team found that the local SIF inspection team had control of returned product. The local SIF inspection personnel had applied official tags and tape surrounding the lots of retained product and were maintaining a case file for verification of the accountability of product determined to be recalled by the establishment and that the disposition of product is conducted as their approved action plan denoted by the CCA or State Office.

The CCA was not able to demonstrate that Brazil has regulations, policies, or procedures that address the CCA's oversight of product recalls when there is reason to believe that such product is adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) and has entered commerce in the U.S. This would include:

- Notification of U.S. authorities
- Response to a finding by an outside laboratory concerning a pathogen or residue violation in exported product
- Verification that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product, and that the consignees have responded accordingly

Noncompliance/nonconformity reports reviewed at each of the four SIF inspection offices were determined to be equivalent to those generated by FSIS inspectors in the U.S. establishments.

The CCA uses Enforcement Investigation Analysis Officer (EIAO) type methodology to conduct audits of the state offices, local inspection offices and the establishment's food safety programs. State auditors conduct bimonthly supervisory reviews of the establishment's food safety programs and a SIF program review and performance evaluation similar to the FSIS In-Plant Performance System (IPPS). The CCA and State offices were conducting audits including the documenting and verifying corrective actions as their program is designed.

All establishment noncompliances were addressed in action plans proffered to the CCA by the establishment. Noncompliances that were identified by SIF inspection were also addressed in action plans submitted by the VIC. Once the action plans were accepted by the state office, the VIC verified that each item in the action plan was completed and acceptable. Documents reviewed reflected these observations.

Documents reviewed at the state offices demonstrated that the CCA took elevated enforcement actions in response to noncompliances identified during International Export and Import Programs Coordination Division (CGPE) audits. These included the suspension of export activities (export certification) to all countries at two establishments and the suspension of production at one establishment. The establishments remained suspended until all noncompliances were corrected and verified.

Documents reviewed at each government oversight level reflected the conditions observed during the on-site visit to each establishment.

The audit included the verification of corrective actions taken by the CCA in association with previous audits conducted by FSIS from 2005 through 2009. The auditors' review of CCA documents indicated that the CCA has a system in place that addresses the deficiencies identified in those audits through the documentation, implementation, verification, and the analysis of those corrective actions and preventive measures and that the CCA has demonstrated process control.

Adequate Administrative and Technical Support

The audit of Brazil's microbiology laboratories was not in the scope of this audit. The Coordination Office of Laboratory Support (CGAL) conducts biannual audits of the one government and four private microbiology laboratories that conduct analysis of products that are destined for export to the U.S. Five audit reports conducted by CGAL in 2010 were reviewed. The audits focused on approved FSIS Microbiology Laboratory Guidebook (MLG) methods: calibration of equipment, internal audits conducted by laboratory quality assurance, traceability of samples and sample analysis, test kits and media, ISO 17025 requirements, and verification of corrective actions for previous noncompliances. No concerns were identified during the review of these reports.

The residue laboratory audits focused on analyst qualifications, 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 CCA has developed and implemented a chemical residue control program. The Coordination and Control of Residues and Contaminants (CCRC) furnished information stating that Brazil's chemical residue control program for 2010 was being followed and was determined to be on schedule.

Two government residue laboratories were audited in order to verify the CCA's ability to provide adequate technical support to the inspection system.

- LANAGRO Residue Laboratory located in Campinas, Sao Paulo
- LANAGRO Residue Laboratory located in Porto Alegre, Rio Grande do Sul

The CGAL conducts annual audits of the residue laboratories that conduct analysis of products that are destined for export to the U.S. The August 13-14, 2008 and the February 19, 2009 audit reports were reviewed, for Campinas, Sao Paulo and the February 13, 2010 audit report for Porto Alegre, Rio Grande do Sul was reviewed. No concerns were identified as a result of the review of these reports.

Both laboratories were conducting analysis for Brazil's National Plan for the Control of Residues and Contaminents (PNCRC). The laboratory located in Porto Alegre was also conducting analyses of validation samples for Ivermection in muscle tissue in order to verify the implementation of the establishment's residue and contaminants control program.

The CCA demonstrated process control of residue laboratories. However, the FSIS auditor made several observations, which raise some concerns, which did not impact the CCA's ability to provide technical oversight such as:

Analysts receive check samples monthly or once or twice a year. Check samples were distributed, in some instances, in a round robin method, which did not allow for the monitoring of the validity of test procedures and quality control procedures that monitor the entire method of analysis.

Recoveries are technically run in both labs, but not all are plotted on control charts at some locations. The charts that are plotted are section control charts. In some instances, laboratories appear to use "set standards" for control limits (SANCO 10684/2009, CODEX, EU 657).

Root cause analysis was not present with at least one corrective action report. One example was for an external proficiency testing failure for lead analysis.

The CCA has revised and partially implemented a control program for Ivermectin and other medium risk compounds such as Cadmium, Lead, and Zeranol. The FSIS auditors reviewed records and programs at the CCA, state offices, local SIF inspection offices, and at establishments audited. The establishments are responsible for conducting a hazard analysis for contaminants and veterinary drug residues. The CCA is responsible for verifying the establishments are in compliance.

The FSIS auditors determined through the records review process that the CCA was compliant with proposed corrective actions for the control of Ivermectin in beef products and compliant with applicable CCA circulars, which describe the implementation of the Ivermectin control program.

Control measures that have been taken by the CCA to ensure that all other residue violations are not likely to occur so that meat products being exported to the U.S. do not have violative residue levels. The following measures have been developed, or have proposed implementation timelines, or have been implemented:

- A statistical assessment of the prevalence of Ivermectin in bovines within the PNCRC was made by the CCA.
- The CCA has commited to conduct an analyses of validation samples for Ivermection in muscle tissue in order to verify the implementation of the establishment's residue and contaminants control program. Phases I and II have been completed. The final Phase, Phase III, was scheduled to start October 4, 2010.
- The CCA has commited to final product testing in muscle, by the CCA, for Ivermectin in products destined for export to the U.S.
- FSIS auditors determined the CCA was in compliance with recently issued Circulars that described the implementation of the Ivermectin control program.

The Brazil CCA was able to demonstrate process control of their inspection system controls and their Ivermectin control program.

However, the CCA was not able to demonstrate National regulatory oversight of the verification of the effectiveness of the product recall system, which consisted of regulations, policies and standard operating procedures. The individual establishments are responsible for the entire process of conducting recalls. No recall effective checks are performed by the CCA to ensure if the recall process was successfully implemented in indentifying, notifying and retrieving the product, which is being recalled for process control.

A trend analysis indicated an improvement in process control by the CCA when comparing 2009 data with 2010 audit results for this component.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations.

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, equipment, daily inspection and periodic supervisory visits to official establishments.

The FSIS auditors reviewed the regulatory authority maintained by the CCA in official legislation, official circulars and official instructions. Controls were in place to grant the states and SIF offices the regulatory authority to enforce requirements for humane

handling and slaughter of livestock, ante-mortem inspection of animals, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to official establishments.

Three state offices were visited to determine if the state maintained adequate government oversight in the implementation of the CCA's food inspection system.

In addition, four establishments were audited. The auditors reviewed the food safety programs of the establishments and records maintained by the local inspection offices, which had regulatory oversight over these establishments.

During July/August 2009 audit, no systemic findings were reported within this audit year concerning this component. No systemic findings were identified during this current audit. A trend analysis indicated a continued improvement in process control by the CCA when comparing 2009 data with 2010 audit results for this 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 FSIS auditors reviewed the official legislation, official circulars and official instructions, which provided regulatory authority by the CCA for sanitation, for sanitary handling of products, and for the development and implementation of SSOP procedures. Controls were in place to grant the states and SIF offices the regulatory authority to enforce sanitation requirements.

Three state offices were visited to determine if the state maintained adequate government oversight in the implementation of the CCA's food inspection system sanitary requirements.

In addition, four establishments were audited. The auditors reviewed the food safety programs of the establishments and records maintained by the local inspection offices, which had regulatory oversight over these establishments.

During July/August 2009 audit, seven sanitation noncompliances for SSOP implementation were reported within this audit year concerning this component. No systemic findings were identified during this current audit. A trend analysis indicated a continued improvement in process control by the CCA when comparing 2009 data with 2010 audit results for this component.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT 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 FSIS auditors reviewed the official legislation, official circulars and official instructions, which provided regulatory authority to the CCA, which requires that each official establishment develop, implement, and maintain a HACCP plan. Controls were in place to grant the states and SIF offices the regulatory authority to enforce HACCP requirements.

Three state offices were visited to determine if the state maintained adequate government oversight for the implementation of the CCA's meat food inspection system, HACCP requirements.

In addition, four establishments were audited. The auditors reviewed the food safety programs of the establishments and records maintained by the local inspection offices, which had regulatory oversight over these establishments.

During July/August 2009 audit, HACCP noncompliances were reported for the inadequate design of some HACCP plans. No systemic findings were identified during this current audit. A trend analysis indicated a continued improvement in process control by the CCA when comparing 2009 data with 2010 audit results for this component.

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.

During July/August 2009 audit, no systemic findings were reported within this audit year concerning this component. One violation for Ivermectin was identified at U.S. POE in fiscal year 2009.

FSIS detected twenty-two Ivermectin violations at U.S. POE between March 26 and June 1, 2010. FSIS conducted additional sampling on May 17 and 18, 2010 for products that were distributed in the U.S., ten confirmed positive samples for Ivermectin were detected.

The trend analysis conducted of POE result data from 2009 and 2010, demonstrated a lack of process control of Brazil's chemical testing program and lack of adequate oversight of the chemical testing program by the CCA for this component.

The CCA had proffered corrective actions and control measures have been taken by the CCA to ensure that all other residue violations are not likely to occur so that meat products being exported to the U.S. do not have violative residue levels.

The FSIS auditors determined through the records review process that the CCA was compliant with proposed corrective actions for the control of Ivermectin in beef products and compliant with applicable CCA circulars, which describe the implementation of the Ivermectin control program. No systemic findings were identified during this current audit. Individual laboratory findings are reported in the government oversight section of this report.

10. CCA MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditors 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 U.S. are safe and wholesome.

The CCA has a *Salmonella* testing program for chilled beef carcass sampling that meets FSIS *Salmonella* Performance Standards requirements. Brazil requires that one *Salmonella* set be scheduled per year that consists of 82 samples from beef carcasses with one positive sample considered acceptable and two positive samples considered a set failure. If an establishment fails three consecutive sample sets, the establishment is removed from the list of establishments eligible to export to the U.S.

The CCA conducts verification activities that monitor the establishment's generic *E. coli* testing program in chilled beef carcasses. The testing program complied with FSIS requirements and Brazil's CCA requirements.

Brazil requires that establishments that export Ready-To-Eat (RTE) products to the U.S. have a program in place to meet FSIS requirements for *Listeria monocytogenes*. Brazil establishments utilize the FSIS *Listeria* Sentinel Site Program along with information from the *Listeria* Compliance Guideline to formulate their *Listeria* program. Brazil has a verification-testing program in place to test for *Listeria monocytogenes* and *Salmonella* species in products that are eligible to be exported to the U.S.

Brazil currently exports beef products to the U.S. that has undergone a lethality treatment for the destruction of the Foot and Mouth Disease (FMD) virus however, Brazil does not have a current strategy or a testing program for the detection of *E. coli* O157:H7. FSIS has the current expectations that countries exporting to the U.S. are required to maintain equivalent standards to FSIS, with respect to their authority, implementation, verification and enforcement of regulations. It is FSIS' expectation that Brazil, which exports beef products to the U.S. consider equivalent sanitary measures that are in place in Brazil.

During July/August 2009 audit, no systemic findings were reported within this audit year concerning this component. No systemic findings were identified during this current

audit. A trend analysis indicated a continued improvement in process control by the CCA when comparing 2009 data with 2010 audit results for this component.

11. EXIT MEETING

An exit meeting was held in Brasilia on September 22, 2010, with DIPOA. At this meeting, the preliminary findings from the audit were presented by the FSIS lead auditor.

The CCA understood and accepted the findings.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The CCA was not able to demonstrate National regulatory oversight of the verification of the effectiveness of the product recall system, which consisted of regulations, policies and standard operating procedures. The CCA presented a circular to the FSIS audit team at the exit meeting on September 22, 2010 that stated, "Weekly data will be consolidated by the central level, aiming at verification of the efficiency of procedures for "recall" executed by Brazilian companies. This information will be sent to FSIS to monitor the recall in the United States". However, the CCA did not present a procedural document stating how the recall verification procedures will be implemented or when the procedure will be implemented.

The CCA demonstrated process control of residue laboratories. However, the FSIS auditor made several observations, which raise some concerns, which did not impact the CCA's ability to provide technical oversight.

For many years, Brazil's meat industry has operated under the constraints of APHIS regulations in association to foot-and-mouth disease (FMD). In that treatments are typically sufficient to destroy any additional food-borne pathogens present, product safety has relied extensively on the correct application of these processes. During the current audit, it was noted that there were few strategies in place by the CCA to address the adulteration of raw ground beef (or beef components) by *E. coli* O157:H7. Should changes in Brazil's disease status occur permitting export of this product type, it is FSIS' expectation that the CCA develop a control program for *E. coli* O157:H7, which reflects a focus on methods to prevent contamination, the inclusion of government and industry verification testing, and any applicable training of its inspection personnel.

Leader Auditor:
Don Carlson, DVM
Senior Program Auditor

Don Carlson, DVM

13. ATTACHMENT TO THE AUDIT REPORT

Attachment 1

Brazil's Response to the Draft Final Audit Report

Brazil's response to the Draft Final Audit Report was received November 18, 2010. Brazil agreed that the FSIS audit findings were accurately described in the audit report.

There was one systemic non-compliance identified under the Government Oversight Equivalence Component: "The CCA was not able to demonstrate National regulatory oversight of the verification of the effectiveness of the product recall system, which consisted of regulations, policies and standard operating procedures." The CCA provided Circular N° 041/2010/DIPOA, November 17, 2010 which defines the directives and procedures for the official verification of recall activities. The design of this circular is similar to the FSIS recall directive "FSIS Directive 8080.1, Revision 5, dated 11/17/08" and should be effective if it is properly implemented.