USDA

United States Department of Agriculture

APR 16 2014

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

Dr. Leandro Diamantino Feijó
Director
Department of Inspection for Products of Animal Origin - DIPOA
Ministry of Agriculture, Livestock and Food Supply - MAPA
Office of Agricultural Protection – SDA
Brasilia DF, Brazil

Dear Dr. Diamantino Feijó:

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Brazil's Meat inspection system from February 18 through March 14, 2013. Enclosed is a copy of the final audit report. The comments received from the government of Brazil are included as an attachment to the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me by telephone at (202) 720-6400, facsimile at (202) 720-7990, or e-mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

BRAZIL

FINAL AUDIT REPORT

January 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from February 18 - March 14, 2013, to determine whether Brazil's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled.

The audit was designed to determine the equivalence of Brazil's meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, the audit also included three special emphasis areas: First, FSIS sought to verify that the corrective actions proffered by the Central Competent Authority (CCA) in response to the September 2010 audit finding - inadequate process control of chemical residues, particularly Ivermectin, and an ineffective recall process - were being implemented. Second, FSIS in conjunction with the Animal and Plant Health Inspection Service (APHIS) examined the CCA's Specified Risk Materials (SRM) and Bovine Spongiform Encephalopathy (BSE) Control Programs in association with detection of the recent BSE case in Brazil to verify that they had been effectively implemented. Third, FSIS audited for the first time, the CCA's oversight and inspection activities to verify food safety in swine establishments that have been recently approved to export to the United States.

The audit findings are summarized below and further addressed in the respective sections of the report.

- The CCA did not provide a standard guideline/circular to its inspection personnel concerning the definition of SRM in cattle in accordance with FSIS' requirements cited in 9 CFR 310.22, resulting in inconsistent implementation of the SRM requirements throughout the system;
- The CCA's ready-to-eat (RTE) verification program did not include on-going verification sampling of food contact surfaces and environmental (non-food contact surfaces) in accordance with FSIS' equivalence criteria for control and prevention of *Listeria monocytogenes* in RTE products;
- The CCA's inspection personnel did not fully enforce HACCP requirements concerning the contents of HACCP plan and record keeping requirements in five audited establishments;
- The CCA's inspection personnel conducted periodic supervisory reviews at a lower than intended bimonthly frequency in the two swine establishments audited; and
- The CCA's inspection personnel did not fully enforce the CCA's sanitation requirements to prevent cross-contamination of bovine carcasses on the rail-out loop in one slaughter establishment.

The audit results indicate that Brazil's inspection system is performing at an "adequate" level in maintaining its equivalence.* However, the onsite audit findings and the post-audit POE violations raise concerns about the CCA's government oversight of implementation of all Circular Policies that include the evaluation of hazard analysis, monitoring, verification, corrective actions, record keeping, hands-on verification of HACCP programs, and the Criteria and Audits for evaluation of the reassessment of HACCP plans in regard to Ivermectin controls. FSIS needs a response from Brazil within 60 days to support Brazil's ability to effectively verify that establishments will conduct a hazard analysis, implement controls, and oversee controls to prevent future Ivermectin violations. In addition, the response will need to demonstrate that the CCA will continually evaluate whether establishments are complying with respect to Ivermectin residue levels, and that the CCA will react if it finds any evidence that compliance is slipping. Until Brazil has satisfactorily addressed these issues, FSIS will not certify any new establishments as eligible to export to the United States. FSIS expects the CCA to address these issues within 60 days of the issuance of this report.

During the exit meeting, the CCA noted that it had taken immediate actions to address the onsite audit findings and had begun to implement long-term remedies for all findings as well. FSIS will evaluate any information provided by Brazil including the submittal of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions through its ongoing equivalence verification methodology.

*FSIS categorizes equivalent countries into three levels of performance: adequately performing, average performing, and well performing. For each category, FSIS has guidance for the frequency of onsite audits and scope of the onsite audits. For additional information about FSIS' Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspections, please see the FSIS' website at: www.fsis.usda.gov/PDF/Performance_Based_Approach_Equivalence_Verification_0213.pdf

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Brazil's meat inspection system from February 18 to March 14, 2013.

Brazil is eligible to export beef and pork products to the United States. From January 1 - December 31, 2012, Brazil exported 16,458,670 pounds of beef products to the United States of which 5,227,334 pounds were re-inspected by FSIS' import inspectors at point-of entry (POE). A total of 56,933 pounds of beef were rejected at POE for non-food safety reasons (e.g., labeling issues or packaging/transportation damages). Brazil exports the following categories of beef products: thermally processed/commercially sterile, not heat treated shelf stable, heat treated shelf stable, and fully cooked not shelf stable. Brazil has not exported any pork products to the United States since approval of swine establishments in January 2012.

This audit was conducted pursuant to the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7)
- 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 this audit of Brazil's meat inspection system included (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process, and (2) any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS's overall goal for the audit was to verify that Brazil's food safety system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objective of determining whether each component continues to be equivalent to that of the United States. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the September 2010 FSIS audit were being implemented. Then, FSIS in conjunction with the Animal and Plant Health Inspection Service (APHIS) examined the CCA's Specified Risk Materials (SRM) and Bovine Spongiform Encephalopathy (BSE) Control Programs in association with detection of the recent BSE case in Brazil. Finally, FSIS also audited the CCA's oversight and inspection verification activities over newly added swine establishments.

The first special area of emphasis was to conduct a follow up examination of the CCA's corrective action in response to the previous FSIS audit which was conducted from August 31 - September 22, 2010. During that audit, no notice of intent to delist (NOID) or delistment was issued. However, the FSIS audit team identified weaknesses in regard to inadequate process control of chemical residues and an ineffective product recall process. The 2013 FSIS auditor closely examined CCA's response to these 2010 findings including long-term remedies (detailed discussion is in the Chemical Residue Control Programs Component section of this report).

The second special area of emphasis was determined as a result of a recent detection of a BSE case in Brazil[1]. USDA decided that part of this audit would be conducted as a joint project with APHIS. Representatives from both agencies conducted onsite audit of Brazil's SRM and BSE Control Programs from February 18 - 22, 2013, to verify that they had effectively implemented. Programs for controlling BSE were verified by APHIS, USDA's agency responsible for animal health, whereas FSIS focused on determining whether control programs precluded SRM from human food. FSIS's audit findings related to SRM Control Programs are described in detail under the HACCP Systems Component Section. APHIS communicated its audit finding directly to the CCA.

The third special area of emphasis was to conduct an examination of the CCA's oversight and inspection personnel activities to verify food safety in swine establishments that have been recently approved to export to the United States. During this audit, FSIS audited for the first time Santa Catarina's State office and two swine producing establishments in the area that were identified by the CCA as eligible for export to the United States in January 2012.

III. AUDIT METHODOLOGY

In conducting this equivalence verification audit, FSIS utilized its established four phase process: plan; execution (onsite); evaluation; and feedback. Each phase is described below.

The first phase involved document and data review and analysis of previous audit findings and other available information. Therefore, prior to conducting the 2013 onsite audit, the FSIS auditor examined CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results and other data collected by FSIS since the last FSIS onsite audit in 2010. In addition, FSIS reviewed information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for first determining the performance level of the CCA's equivalent system[2] and then planning the onsite audit itinerary.

---

[1] The World Animal Health Organization (OIE) announced on December 7, 2012, that Brazil reported its first case of BSE. OIE reported that a 13-year old beef breeding cow died on December 18, 2010. OIE noted that samples from the cow were initially tested for rabies and the cow was properly buried on site. In April 2011, a negative histopathological result for BSE was obtained. Then in June 2012, the sample was sent to another laboratory for BSE diagnosis and it tested positive. Brazil sent the sample for confirmatory diagnosis to England and it was confirmed positive in December 2012.

[2] FSIS categorizes equivalent countries into three levels of performance: adequately performing, average performing, and well performing. For each category, FSIS has guidance for the frequency of onsite audits and scope of the onsite audits. For additional information about FSIS' Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspections, please see the FSIS' website at:
http://www.fsis.usda.gov/PDF/Performance_Based_Approach_Equivalence_Verification_0213.pdf

The second phase of the audit was the onsite or execution phase. FSIS conducted this onsite audit to verify the CCA's oversight activities through onsite document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, the Department of Inspection for Products of Animal Origin (DIPOA), including members from the state or establishment inspection offices.

Auditor reviewed management, supervision, and administrative functions at the CCA headquarters, Santa Catarina State office, and five establishments (two bovine slaughter/processing, one bovine processing only, and two swine slaughter/processing establishments) to determine whether the national system of inspection, verification, and enforcement is being implemented as required. During the establishment visits, particular attention was paid to the extent to which the CCA ensures the control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 of the U.S. Code of Federal Regulations (CFR), section 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories during the planning phase and this execution phase. FSIS reviewed laboratory related data collected prior to the 2013 audit through analysis of documents in the self-reporting tool (SRT). Second, FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters. An onsite visit to the laboratories associated with the chemical residue and microbiological testing programs was not on this year's audit itinerary.

The third phase of the audit was an evaluation. FSIS conducted a post-audit evaluation of all data collected onsite to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. When evaluating the audit data cumulatively, FSIS determined that CCA provides an equivalent level of protection as provided by the U.S. inspection system, though some problems were noted. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit was feedback, which begins with this draft audit report providing the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, FSIS and the CCA mutually develop an action plan to address any issues raised by the audit. These issues will be tracked by FSIS until resolution and will be automatically included as areas of special emphasis in the next onsite verification audit.[3]

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be

[3] For additional information about any of the USDA final audit reports for Brazil's Food Safety System, please see the FSIS' website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses and corrective actions provided in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

Oversight

The DIPOA, is under the CCA's Ministry of Agriculture, Livestock and Supply (MAPA). The DIPOA has several divisions including General Coordination for Inspection, General Coordination for Special Programs, and International Export and Import Programs Coordination Division which are involved with production of meat product destined for export to the United States. DIPOA ensures uniform implementation of regulatory requirements and is responsible for oversight of the official activities of inspection personnel at establishments eligible to export to the United States.

The CCA's authority to enforce inspection laws is specified in Brazil's statute, *Regulations for the Inspection of Industrial Sanitation for Products of Animal Origin (*RIISPOA). The CCA has the legal authority and the responsibility to write, implement, and enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. To achieve these objectives, the CCA issues, distributes, and enforces a number of official circulars that are inspection-related guidelines and instructions to its inspection personnel.

At the state level, the State Inspection Service of Products of Animal Origin (SIPOA) represents DIPOA. SIPOA offices operate within the scope of the inspection operations coordinated by DIPOA and are responsible for the implementation and enforcement of inspection operations in the slaughterhouses, processing plants, and cold storage facilities within the state. This is the level of government that also provides periodic supervisory reviews for the U.S.-eligible establishments. At the establishment level, the Federal Inspection Service (SIF) has responsibility to implement and enforce inspection laws at the establishments eligible to export meat products to the United States.

The FSIS auditor reviewed non-compliance reports (NRs) that were generated by in-plant inspection personnel at all five audited establishments. FSIS noted that the inspection personnel had identified and documented deficiencies in NRs using the same format as FSIS' NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditor reviewed all open and closed NRs issued from September 1, 2012, to the day of the audit. The auditor determined that the inspection personnel have adequately described non-compliances (e.g., product residue on the food contact surfaces of equipment during pre-operational inspection verification) and verified the effectiveness of the establishment's corrective actions (e.g., establishment's preventive measures to control condensation). The FSIS auditor also reviewed the last 12 months of written periodic supervisory reviews to assess the enforcement capability of the inspection

personnel and the adequacy of establishment's corrective actions. The conditions in the audited establishments matched the supervisory reviews, and no non-compliance trends related to Sanitation Standard Operating Procedures (SSOP), HACCP, Sanitation Performance Standards (SPS), or slaughter activities were observed.

FSIS looks to see whether documented periodic supervisory reviews are performed in all establishments eligible for export to the United States. The auditor verified implementation of these reviews at the CCA headquarters, the Santa Catarina SIPOA office, and all audited establishments. In the two bovine slaughter establishments and one bovine processing establishment audited, periodic supervisory reviews were conducted bimonthly by the state veterinary supervisors employed by the responsible SIPOA state office in accordance with Circular No 874/2008, Circular No 742/2008, and Circular No 27/2008. However, the Santa Catarina SIPOA office did not follow its established bimonthly frequency of supervisory reviews in two audited swine slaughter/processing establishments. The CCA's written frequency requires a minimum of six supervisory reviews per year for each of the U.S.-eligible establishments, but only one supervisory review at each swine establishments had been conducted since their approval in January 2012. The auditor noted that none of the U.S.-eligible swine establishments has exported any products to the United States since their approval by the CCA.

In all locations, the supervisory reviews were conducted using a standard form, "*Relatorio De Supervisao*," which consists of a detailed checklist with two main parts. The first part (*Programa De Autocontrole*) consists of sections for evaluating the adequacy of establishment food safety systems including items related to inspection verification of SPS elements, SSOP, HACCP, and microbiological control (i.e., generic *E. coli*, *Salmonella,* and *Enterobacteriaceae*). The second part (*RelatorioDe Avaliacao das Atividades de Inspecao*) consists of questions for evaluating the knowledge, skills, and abilities of inspection personnel to conduct assigned responsibilities at the U.S.-eligible establishments. The periodic supervisory review report is distributed to the audited establishment's management, official veterinarian (OV), and the related SIPOA office. The OV is responsible for verification of corrective actions resulting from the review. The SIPOA office is responsible for analyzing the results of the review. The SIPOA office also reviews the establishment's action plans and the verification of the corrective actions by the OVs in order to verify the effectiveness and implementation of action plans.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The CCA has adopted FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416. The in-plant inspection personnel at all audited establishments' verify sanitary conditions in accordance with methodology described in the CCA's Circular 175/2005, which includes the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures. This circular provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of inspection activities during routine verifications of sanitation issues including: maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization ; hygiene, hygienic habits, and the workers' health; and operational sanitary procedures.

After a thorough review of all documents, onsite observations, and interviews, the auditor concluded that Brazil's government has in place an equivalent organizational structure for performing oversight. In fact, based on onsite findings, during the inspection personnel strike at the CCA's headquarters from August 6-9, 2012, oversight continued as required. In order to verify the potential impact of this strike on the CCA's oversight of the U.S.-eligible establishments, the FSIS auditor interviewed inspection personnel at the CCA headquarters, one state office, and five audited establishments, and reviewed daily inspection records generated by in-plant inspection personnel from August 6-9, 2012. The auditor noted that the CCA managed a staggered work schedule for its headquarters personnel and was able to continue to meet its oversight responsibilities during the strike. Therefore, there was no interruption in the CCA's functions for implementation of regulatory requirements in the U.S.-eligible establishments.

The auditor also confirmed compliance with the CCA's Circular Notice No 14/DIPOA/2005, which provides the regulatory framework for payment for inspection activities. The auditor verified, through document review (i.e., pay stubs and ID cards) at the CCA, state office, and audited establishments that inspection personnel assigned to the U.S.-eligible establishments are employees of the government, including national, state, and municipal governments.

Post-audit findings of four POE Ivermectin violations in product from two separate establishments between February 19, 2013, and August 5, 2013, raise additional concerns that require an examination of establishments' HACCP plans, as well as of the adequacy of supervisory oversight at all levels of Brazil's inspection system.

In conclusion, considering the audit and post-audit POE findings, FSIS finds that the CCA provides HACCP requirements equivalent to those of FSIS' HACCP regulatory requirements. In-plant veterinary officials and supervisors monitor, verify, and enforce the implementation of most of the HACCP regulatory requirements in the audited establishments. However, there is a question about the adequacy of the CCA's verification of the establishments' hazard analysis given the recurrence of the Ivermectin problem that needs to be addressed. Also, there is a question about inspection and supervisory oversight in the establishment. These questions need to be addressed by the CCA within 60 days of the date of issuance of this audit report.

Swine Establishments

The CCA certified five swine slaughter/processing establishments as eligible for export to the United States for the first time in January 2012. In order to verify the CCA's oversight, FSIS conducted an onsite audit of Santa Catarina SIPOA state office and two swine producing establishments. During the onsite review of the SIPOA office, the FSIS auditor interviewed SIPOA inspection officials and requested the state's inspection records pertaining to approval of the swine producing establishments, including electronic and printed versions of two audited swine establishment registration forms, SIPOA's initial approval documents, and the CCA's audit and final certification documents.

The FSIS auditor verified that the CCA and SIPOA offices are both involved in the initial and annual ongoing certification of eligible swine establishments for export to the United States. The CCA has the sole authority and responsibility to grant final certification of a new establishment

or to permit an existing establishment to maintain its eligibility to export to the United States. Circular No 228/2005/CGPE/DIPOA (inspection report) and Circular No 27/2009/DIPOA (inspection requirements) describe the procedures that an establishment must follow to obtain approval from DIPOA to become certified for export and the actions that DIPOA and SIPOA officials are to take at each step of the approval process. The SIPOA conducted an initial export approval determination through comprehensive establishment audits which consisted of review of each establishment's written programs for HACCP, sanitation, and microbiological sampling, as well as onsite visits prior to final approval.

During the onsite audit of two swine slaughter/processing establishments, the FSIS auditor conducted a comprehensive review of both establishments and of inspection documents covering the verification of the six equivalence criteria components including: SPS, SSOP, HACCP programs, periodic supervisory reviews, *Salmonella* spp. testing, and generic *E. coli* testing. The auditor also confirmed that CCA inspection personnel conducted the approval process in accordance with the CCA-prescribed procedures cited in Circular No 228/2005/CGPE/DIPOA and Circular No 27/2009/DIPOA.

FSIS' onsite audit verification methodology including observations, document reviews, and interviews in combination with FSIS' pre-audit SRT document analysis of the CCA's control measures demonstrate that the CCA continues to meet FSIS equivalence criteria at an adequate level of performance for this component. However, the onsite audit findings indicate a need for the CCA to improve its oversight activities including sanitation and HACCP verification procedures.

V. COMPONENT TWO: 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. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits in the U.S.-eligible establishments.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the system. The FSIS auditor verified that official inspection and verification activities are in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA as outlined in official legislation, circulars, and other instructions issued in accordance with RIISPOA inspection law. The auditor confirmed that the CCA provides the SIPOAs and SIF establishment inspection offices with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment

construction, facilities, equipment, daily inspection, and periodic supervisory visits in the U.S.-eligible establishments.

During the onsite audit of two bovine and two swine slaughter establishments, the FSIS auditor observed the in-plant inspection verification activities for pre-operational and operational sanitation procedures (described under Component Three), HACCP verification activities including the zero tolerance Critical Control Point (CCP) verification (described under Component Four); ante-mortem/humane handling inspection examination; post-mortem examination; *Salmonella* spp. and generic *E. coli* sample collection (described under Component Six). In addition, during the onsite audit of one bovine processing establishment, the FSIS auditor reviewed and observed the in-plant inspection verification activities for RTE sampling and testing.

The FSIS auditor verified that in-plant OV conducts ante-mortem inspection on the day of slaughter by reviewing the in-coming registration and identification documents including Animal Movement Permits (GTA) and Animal Identification Documents (DIA). In accordance with procedures outlined in the SRT, the OVs observe all animals at rest and in motion from both sides in designated holding pens in order to determine whether they were fit for slaughter. Each establishment has a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals); and that if animals are held overnight, feed and water are provided. The implementation of ante-mortem inspection is in compliance with Brazil's RIISPOA, Title VII-Chapter I-Ante-mortem Inspection which FSIS has determined to be equivalent. The FSIS auditor further verified through onsite record review, interviews, and observations that the CCA's requirements concerning ante-mortem and humane handling/slaughter of livestock are being met in all audited slaughter establishments.

FSIS assessed post-mortem inspection examinations through onsite record review, interviews, and observations of inspection activities in all audited slaughter establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. Both in-plant veterinary and non-veterinary inspectors are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with Brazil's RIISPOA, Title VII, Chapter III-Post-mortem Inspection, which FSIS has determined to be equivalent. The design of the post-mortem inspection stations, including proper lighting and the number of on-line inspectors, are in accordance with inspection requirements. The FSIS auditor also observed the functions of the off-line veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities in all audited establishments. These daily verification activities include direct observation and review of establishment's records, including HACCP, SSOP and SPS, and *E. coli* and *Salmonella* carcass sampling records.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to

prevent direct product contamination or insanitary conditions. The CCA has adopted FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416. The in-plant inspection personnel at all audited establishments verify sanitary conditions in accordance with methodology described in the CCA's Circular No 175/2005/CGPE/DIPOA, "Verification Procedures for the Self-Inspection Programs". This includes the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures. This circular provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of establishment activities during routine verifications of sanitation issues including: maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits, and the workers' health; and operational sanitary procedures. FSIS also assessed the adequacy of HACCP program verification activities conducted by inspection officials at the establishment level by observing verification activities and reviewing monitoring and verification records generated by establishment and in-plant inspection personnel at all audited establishments.

The CCA's Circular No 463/DCI/DIPOA dated August 4, 2004, *"Materials of specified hazard for Bovine Spongiform Encephalopathy (BSE) and other requirements of the legislation of the United States,"* correctly defines the SRM in cattle as (1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age or older, and (2) the tonsils and the distal ileum of all cattle. This definition is consistent with FSIS' 9 CFR 310.22 definition of SRM. However, the CCA's more recent Memo Circular No 001/CGI/DIPOA dated January 23, 2007, *"Guidelines for removal, segregation and disposal of SRM,"* only defines the brain, eyes, spinal cord, tonsils, and distal ileum as SRM for all cattle. As this document did not identify the skull, trigeminal ganglia, vertebral column, and dorsal root ganglia as SRM in bovines 30 months of age or older, this definition is not consistent with FSIS' definition of SRM found in 9 CFR 310.22.

Brazil's meat inspection system has legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the U.S. system of meat inspection. FSIS' onsite audit verification methodology including observations, document reviews, and interviews in combination with FSIS' pre-audit SRT document analysis of the CCA's statuary authorities demonstrate that the CCA continues to meet the core equivalence requirements for this component. However, FSIS finds that the CCA operates at an adequate level of performance because periodic supervisory reviews at two audited swine establishments were not conducted at the scheduled frequency. In fact, the CCA conducts its supervisory reviews at a much lower frequency than the intended bimonthly frequency. FSIS expects that the CCA adhere to its established frequency of periodic supervisory reviews or provide documentation describing the change in frequency of supervisory reviews it will conduct to ensure that the FSIS standards are being met.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation.

To be considered equivalent to FSIS' program, the CCA must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the onsite portion of the audit, the auditor reviewed and analyzed Circular No 175/2005/CGPE/DIPOA, "*Verification Procedures for the Self-inspection Programs,*" submitted by the CCA in the SRT. Once onsite, the auditor gathered additional information at the government offices and five of the U.S.-eligible establishments.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all of the audited establishments. In one of the audited establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures begin after the establishment personnel conducted its pre-operational sanitation and determined that the facility is ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the CCA's established procedures.

The FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at all of audited establishments. These verification activities include direct observation of operations and review of the establishments' associated records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspections' verification records for the same time period. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. No concerns arose as the result of these onsite reviews.

At one audited bovine slaughter establishment, the FSIS auditor observed an overcrowded rail-out loop where five bovine carcasses that were awaiting further examination and trimming were in direct contact with each other; thereby creating inadequate sanitary handling of products and providing conditions for potential cross-contamination. The FSIS auditor noted that the CCA has several documents that clarify establishment and inspection personnel responsibilities to prevent cross contamination. The CCA documents that specify that effective measures are to be adopted to prevent contamination of the food material through direct or indirect contact with the contaminated material during the initial processing stages include the following: Bovine Meat Inspection Standardization of Techniques; Facilities and Equipment (page 44); Sanitary Procedures of the Operations Circular No. 175/2005/CGPE/DIPOA; Establishment Hygiene – RIISPOA (Title V, page 36); and Technical Regulation on Hygiene, Sanitary Conditions, and Good Manufacturing Practices for Food Manufacturing and Industrializing Establishments (Administration Ruling No. 368, September 4, 1997). The CCA's inspection officials were in agreement with the FSIS auditor's assessment that the establishment's rail-out procedure was inadequate to prevent carcass accumulation or cross-contamination of these carcasses. The inspection personnel took immediate enforcement action by slowing down the chain speed, making disposition of the affected carcasses, and instructing the establishment to implement further corrective actions.

The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOPs. In-plant veterinary officials and state supervisors enforce the regulatory requirements and monitor the ability of establishments to maintain sanitary conditions. The one noncompliance noted above was addressed. Therefore, the audit findings support the conclusion that the CCA continues to meet FSIS equivalence criteria at an adequate level of performance for this component.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or a similar type of preventative control plan.

The CCA's headquarters, one SIPOA office, and five SIF establishments were visited to determine whether the SIPOA and SIF inspection offices maintained effective government oversight for the implementation of the CCA's meat food inspection system and in particular HACCP requirements. In addition to focus on HACCP plan design and its implementation, the FSIS auditor verified the CCA's oversight activities through onsite record review, interviews, and observations of the implementation of the SRM Control Program at two audited bovine slaughter establishments.

HACCP

Brazil's meat inspection system has adopted FSIS' HACCP regulatory requirements prescribed in 9 CFR Part 417. The CCA imposes on the U.S.-eligible establishments regulatory requirements for the development, implementation, and maintenance of HACCP programs as set forth in this regulation. The FSIS auditor verified through record review and observation that the in-plant inspection personnel at certified establishments conducted daily verification of HACCP plans in accordance with methodology described in the CCA's Circular 175/2005, which includes the evaluation of written HACCP programs, monitoring, verification, corrective actions, record keeping, and hands-on verification inspection. The in-plant inspection personnel verification of HACCP plans includes verification of CCPs for all production shifts. The inspection personnel entered the verification results on Form 01/APPCC.

At four slaughter establishments audited, the FSIS auditor conducted an onsite review of the zero tolerance (feces, ingesta, and milk) CCP records generated over the past six months. In addition, the FSIS auditor reviewed the in-plant inspection's associated zero tolerance verification records (Form 02/APPCC) at these four slaughter establishments. Both establishment and in-plant inspection monitoring and verification records documented a few deviations from the critical limits. The review of the establishment's corrective actions in response to deviation from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance with 9 CFR 417.3, were addressed by slaughter establishment employees and verified by the inspection personnel. No non-compliance trends were detected as the result of these document reviews. Furthermore, the FSIS auditor verified the physical CCP monitoring location by observing inspection personnel conducting HACCP hands-on verification activities, as well as performing

an independent direct monitoring examination of livestock carcasses. No deviation from the critical limits was observed by the inspection personnel or the FSIS auditor. The FSIS auditor also verified that the zero tolerance CCP monitoring location meets the CCA's requirement, including the adequate illumination for proper examination.

During the onsite establishment's document reviews and interviews of establishment personnel, the FSIS auditor identified the following HACCP related problems in audited establishments:

- In one establishment, HACCP verification records (record review and direct observation of monitoring procedures) for zero tolerance CCP did not include the required time for each entry;
- In two establishments, HACCP verification records for review of records component did not document the required time or the results of the ongoing verification activities conducted by the establishment's personnel; and
- In two establishments, the returned product was not included in the establishment's flow chart and hazard analysis.

In order to ensure ongoing compliance with HACCP recordkeeping requirements, FSIS expects the CCA to make corrective actions to improve both the CCA's in-plant HACCP verification activities as well as the manner in which each state conducts its periodic supervisory reviews. Additional HACCP-related training might be beneficial for in-plant personnel.

Post Audit: FSIS has significant concerns about the effectiveness of the CCA's residue (Ivermectin) control program as a result of the post-audit POE violations. FSIS requests an explanation of the corrective actions at the establishment level, including measures to prevent the recurrence of residue violations within 60 days of the date of issuance of this report. These concerns are discussed further in the section of this report on Component Five.

SRM Controls

The FSIS auditor conducted onsite audits of two bovine slaughter establishments in the State of Sao Paulo to review the CCA's SRM control program. The auditor toured these slaughter establishments in their entirety to observe and verify actual operations concerning removal, segregation, and disposal of SRM. In particular, the FSIS auditor reviewed and verified the CCA's verification and control program for SRMs at both ante-mortem and post-mortem inspection examinations. In addition, the auditor thoroughly reviewed relevant documents and records generated by the slaughter establishments and in-plant inspection personnel, as well as conducted interviews with in-plant personnel.

The auditor noted that the CCA has requirements for removal, segregation, and disposal of SRM in cattle and requires that all SRM must be removed prior to export to the United States. However, the two active CCA circulars provide two different regulatory definitions for SRM resulting in confusion among inspection and establishments personnel, as well as, incorrect implementation. This finding was identified through interview of inspection personnel and review of two active, but inconsistent, SRM-related Circulars, No 463 and No 001.

Both circulars are active documents; the Memo Circular No 001/CGI/DIPOA/2007 did not supersede Circular No 463/DCI/DIPOA/2004. The impact from inconsistencies in these two documents became evident when the auditor noted that both the in-plant inspection and establishment personnel applied the inadequate SRM definition based on Memo Circular No 001/CGI/DIPOA/2007. The audited establishments presented written procedures only for removal, segregation, and disposal of brain, eyes, spinal cord, tonsils, and distal ileum and only maintained daily monitoring records for these SRM. Consequently, the skull, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia were omitted from both the written program and related monitoring records. This omission is particularly important because in both audited establishments, all cattle are handled as though they are 30 months of age or older. As a result, the omitted SRMs are not routinely removed, segregated, and disposed of accordingly by establishment personnel. In addition, the in-plant veterinarians are only verifying the establishment's removal, segregation, and disposal of brain, eyes, tonsils, spinal cord, and distal ileum. The FSIS auditor verified that the in-plant inspection personnel perform the verification activities related to SRM removal and document these activities on a daily inspection SRM verification form that include three verification procedures: reviewing records; observing establishment employees performing procedures; and conducting hands-on inspection verification procedures.

In the two bovine slaughter establishments audited, the FSIS auditor also verified through review of verification records generated by inspection personnel and direct observation of inspection activities that the in-plant veterinarians are responsible for identifying and securing all animals that are exhibiting clinical signs of central nervous system (CNS) disorders at the ante-mortem inspection station. At each establishment visited, the auditor confirmed that the onsite veterinarians could appropriately identify the clinical signs associated with CNS disorders that include, but are not limited to: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness. Based on CGI/ DIPOA memo 164/17 September of 2012, *"surveillance of spongiform encephalopathy,"* and Joint Service Instruction No 002/2003 between DIPOA and DSA (Department of Animal Health), all animals exhibiting CNS disorders or offered for emergency slaughter (including non-ambulatory, disabled cattle) are subject to mandatory brain stem sample collection by inspection personnel.

In-plant veterinarians are responsible to complete a form *"Boletim de Necropsia"* for any animal that is subject to emergency slaughter. This form contains inspection information such as slaughter establishment number, animal identification number, species/breed of animal, sex, temperature, approximate weight, reason for emergency slaughter, and a brief description of the ante-mortem findings, the date, and the signature of the veterinarian who conducts the ante-mortem inspection. After the completion of emergency slaughter, which occurs in a designated facility adjacent but separate from the holding pens, a post-mortem/necropsy report documents the results of the veterinary examination on the *"Boletim de Necropsia"*. The facilities visited also presented a designated cutting/boning room connected to the emergency slaughter room. The emergency slaughter/cutting facility is under direct supervision and lock of inspection personnel. All pathology samples, including BSE surveillance brain stem sample collection, occurred at these designated facilities. All animals that are subject to emergency slaughter are

excluded for export to other countries. The CCA and audited establishments have a carcass marking system and related identification records in place to identify these animals/carcasses throughout the inspection system. The FSIS auditor's review of these documents and the related tracking system indicated that no product originating from animals undergoing emergency slaughter are exported to the United States.

The FSIS auditor observed stunning procedures through direct observation. The audited bovine slaughter establishments did not inject compressed air into the cranium of cattle during stunning. In addition to Animal Movement Permit (GTA) and Animal Identification Document (DIA) records for age verification (mentioned earlier in the ante-mortem discussion), both establishment and in-plant inspection personnel conduct 100% hands-on dentition examination during the post-mortem examination as part of the CCA's quality control program for carcass classification. Regardless of animal age or carcass classification, all animals are considered and handled as 30 months of age or older in audited establishments in regard to SRM control.

The FSIS auditor observed each veterinarian's training certificate for BSE sample collection that was organized and signed by SIOPA and DSA officials. This training course was conducted on August 3-5, 2009, and consisted in both theoretical and practical sessions. The classroom portion was 12 hours in duration and included topics such as BSE etiology, MAPA's policy and international trade, OIE status, surveillance actions, mitigation of BSE in the slaughterhouse, collection/separation of SRM in accordance with circular 001/2007, the SRM tracking system data-entry guidelines (SIGSIF), specific instructions for sample collection and submission to the BSE diagnostic laboratory, common mistakes associated with collecting/sending samples, differential diagnosis for similar conditions, BSE mitigation at rendering facilities, and control of sterilization of bone meal. In addition, a hands-on session covered sample collection, preservation, shipment of the brain stem, separation and disposal of SRM, and active surveillance action in slaughterhouses.

The FSIS auditor reviewed the official inspection form entitled "*Collection and Shipment of Brain Stem for Diagnosis of Transmissible Spongiform Encephalopathy,*" to verify the implementation of brain stem samples collection at two audited establishments. In addition, the auditor reviewed the testing records generated by the Lanagro/PE BSE Diagnostic Laboratory and verified that all the BSE testing results related to audited establishments were negative.

The FSIS auditor reviewed NRs issued related to establishments' SRM control and verified that the in-plant inspection personnel take appropriate enforcement action during carcass or head inspection when they observe SRM on edible portions of product, or when an establishment failed to follow its written SRM control program. For example, in one case, an employee did not use the dedicated knife to cut through the spinal cord when separating a bovine head from the carcass in accordance with the establishment's written procedures. In this case, the in-plant inspection personnel stopped the slaughter line, notified the slaughter supervisor, issued an NR, and verified that the establishment took the proper corrective action based on its written SRM control procedures. The corrective actions included extra training of the employees concerning the use of the dedicated equipment, disposing of affected product, and cleaning and sanitizing of equipment.

The results of the pre-audit document analysis and onsite audit verification of the HACCP component indicate that the CCA continues to meet FSIS equivalence criteria at an adequate level for this component. However, the CCA must ensure that the regulatory definition of SRM, is clearly described and communicated through the chain of command. As part of on-going equivalence verification, FSIS will verify compliance by requesting inspection information such as periodic supervisory reviews for the U.S.-eligible producing establishments to establish that the corrective actions have been properly implemented throughout the inspection system.

VIII. COMPONENT FIVE: CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

FSIS' residue experts thoroughly reviewed documentation pertaining to the design and implementation of the CCA's National Residue Program (NRP) prior to this audit. The in-depth review included an analysis of the 2012 and 2013 residue monitoring plan as well as additional responses outlining the structure of Brazil's chemical testing program provided in the SRT. The auditor did not conduct an onsite audit of the residue laboratories.

The CCA's Coordination Office of Laboratory Support (CGAL) conducts annual audits of its residue laboratories that perform analysis of products that are destined for export to the United States. The CGAL applies standard form, "*Relatorio de Auditorial No Laboratorio-RAL,*" to document its audit findings. During the CCA's headquarters audit, the FSIS auditor interviewed CGAL officials and reviewed the following three most recent laboratory audit reports:

- Annual Monitoring Audit of LANAGRO Residue Laboratory, Rio Grande do Sul, December 19-20, 2012. This government residue laboratory conducts Ivermectin testing in muscle;
- Annual Monitoring Audit of LANAGRO Residue Laboratory, Mina Gerais, July 23-15, 2012. This government residue laboratory conducts Ivermectin testing in liver; and
- Follow-up Monitoring Audit of Plantec Laboratory, located in Sao Paulo, September 17-18, 2012. This laboratory is private.

The three CGAL audit reports documented laboratory responses to identified weaknesses including verification of the implemented corrective actions. The FSIS auditor's review found no concerns with the CCA's chemical residue program.

2010 Audit Follow-Up Findings

During the previous FSIS audit in 2010, the audit team identified the following problem:

- 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. Effectiveness checks were not performed by the CCA to ensure that the recall process was successfully implemented identifying, notifying and retrieving the product.

During this 2013 audit, the FSIS auditor conducted a follow-up verification of the CCA's corrective actions. The auditor interviewed inspection officials at the CCA's headquarters office and verified that the CCA had addressed the identified finding by implementing Circular No 041/2010/DIPOA, November 17, 2010. This document defines the directions and procedures for the official verification of recall activities, modeled after FSIS Directive 8080.1, Recall of Meat and Poultry Products - Revision 6, dated 10/26/2010. In addition, the FSIS auditor examined records related to recall procedures and the implementation of corrective actions and preventive measures at the state and establishment inspection levels. This audit confirmed that the CCA had verified the effectiveness of its recall procedures and found them acceptable. Audited establishments demonstrated an integrated traceability system for product, from the farm through distribution, which enabled the identification of lots or units of products in the event of a recall.

During the 2010 audit, a second problem was detected. The CCA failed to ensure that there was an adequate process control for chemical residues, particularly for Ivermectin. FSIS detected 22 Ivermectin violations at U.S. POE from March 26 - June 1, 2010. FSIS conducted additional sampling on May 17-18, 2010, and for products that were distributed in the United States; 10 confirmed positive samples for Ivermectin were detected. The CCA proffered corrective actions and implemented control measures. To verify equivalence, FSIS conducted its 2010 audit. The FSIS auditors determined through onsite review of records that the CCA was compliant with proposed corrective actions for the control of Ivermectin in beef products and compliant with applicable CCA circulars related to the implementation of the Ivermectin control program.

During the 2013 audit, the FSIS auditor specifically verified the implementation and enforcement of the Ivermectin control program at the CCA's headquarters and audited establishments. As part of verification process during this year's audit, the auditor reviewed the following circulars related to Ivermectin control programs:

- Circular No 016/2010/DIPOA: *Audits for the evaluation of the reassessment and revalidation of the HACCP Plans*;
- Circular No 017/2010/DIPOA: *Audits for the evaluation of the reassessment and revalidation of the HACCP Plans*;
- Circular No 018/2010/DIPOA: *Criteria to be used during the audits for the evaluation of the reassessment and revalidation of the HACCP Plans*;
- Circular No 021/2010/DIPOA: *Guidelines for the validation of the CCP limits of the HACCP Plans and the CPs, of the pre-requisite programs*;
- Circular No 022/2010/DIPOA: *Official Program of Avermectin Analysis*;

- Circular No 127/2010/CHC/CGPE/DIPOA: *Use of process control letters to assess the results of monitoring for ivermectin in cattle*; and
- Circular No 198/2010/CHC/CGPE/DIPOA: *Review of Ivermectin in the final product.*

The FSIS auditor through pre-audit review of the aforementioned circulars and during onsite observations, document reviews, and interviews of inspection personnel, at the CCA and establishment levels, noted that the current year's sampling plan is proceeding in the manner outlined in the Ivermectin control plan. The auditor verified that the inspection personnel follow the CCA's instruction in sample collection for those products that are destined for export to the United States.

A review of FSIS' POE testing results for Ivermectin violations in product received from Brazil from 2009 to February 15, 2013, demonstrate an improvement of the CCA's control for this compound, as shown in the following table.

Number of Ivermectin Violations at Point-of-Entry (POE) Testing
FY2009 – First Third of FY2013

	FY2009	FY2010	FY2011	FY2012	FY2013 (First Third)
Number of POE Ivermectin Violations	1	21	1	0	1

FSIS determined that the Chemical Residue Control Programs component includes a national program managed by the CCA. The inspection system has appropriate laws, circulars, and other decrees that serve as the legal authority for the implementation of this program. The CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data.

However, POE sampling results from February 19 - August 5, 2013, showed four violations for Ivermectin. These violations occurred in product produced in two separate establishments. Three violations occurred on February 19, April 24, and May 16 in product from SIF 385. One violation occurred in product from SIF 337 on August 5. Thus far, corrective actions proffered by DIPOA rely on education of the animal producers and voluntary compliance with the stated withdrawal time in order to prevent Ivermectin violations. Further DIPOA will delist the producer from providing cattle to slaughter establishments until multiple tests return negative.

FSIS expects certified establishments to execute policy Circulars 021 and 127 particularly pertaining to the validation of critical control points, control programs, and pre-requisite controls; and the CCA to audit, evaluate and verify HACCP plans and controls as defined in policy Circulars 16, 17, and 18.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized

and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of the CCA's Circular No 175/2005/CGPE/DIPOA, *"Verification Procedures for the Self-inspection Programs,"* previously submitted by the CCA as support for the responses provided in the SRT. This circular describes the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological tests, including *Enterobacteriaceae*, *Salmonella* spp., generic *E .coli,* and *Listeria monocytogenes (Lm)* in RTE products.

The FSIS auditor accompanied and observed the in-plant inspection verification activities for *Salmonella* and generic *E. coli* sample collection in all four slaughter establishments. In addition, the auditor observed and verified the implementation of *Lm* sampling program in the one processing establishment. The auditor did not visit any microbiological laboratories.

The CCA has a *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling that is consistent with the FSIS *Salmonella* Performance standards in 9 CFR 310.25(b). The CCA requires that one *Salmonella* set be scheduled per year that consists of 82 samples from beef (55 samples from swine) carcasses with one positive sample considered acceptable from beef (up to six in swine), and two positive samples considered a set failure. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States. The suspension would remain in effect until the establishment identifies the cause, takes proper corrective actions and preventive measures, and achieves the performance standard set based on number of samples tested (n) and maximum number of positives to achieve standard (c). The CCA's *Salmonella* performance standard for bovine ($n = 82$, $c \leq 1$) and swine ($n = 55$, $c \leq 6$) is the same as FSIS' standards.

The CCA conducts verification activities that monitor an establishment's generic *E. coli* testing program in chilled livestock carcasses. The testing program complies with FSIS equivalence criteria and is outlined in the CCA's Circulars 835/CGPE/DIPOA/2006 and 1058/ CGPE/DIPOA/ 2008. While on site at two establishments, the FSIS auditor observed sampling and verified that the responsible individuals have the knowledge and skills to implement this type of testing on an ongoing basis. Similarly, both the establishment and inspection personnel are familiar with the upper and lower control limits, as well as the correct actions to be taken when the upper limits are exceeded. However, no such loss of process control was identified during the onsite audit and in the documents reviewed for the last six months.

The CCA has a verification-testing program in place to test for *Lm* and *Salmonella* species in RTE products that are eligible to be exported to the United States. In addition, the CCA requires that establishments exporting RTE products to the United States have a program in place to meet FSIS equivalence criteria for control of *Lm*. FSIS' official letter, dated July 13, 2011, clarifies the FSIS's *Lm* policy "Notification of Changes to the FSIS' Equivalence Criteria - Control Program for *Listeria monocytogenes (Lm)* in Ready-to-Eat (RTE) Products," to foreign countries. This Notification stipulates verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment for *Lm* at a frequency that ensures that the

establishments' control measures are effective. Based on the FSIS auditor's interviews and review of inspection documents at the CCA headquarters in Brasilia, the Santa Catarina state office, and one audited processing only establishment, the auditor discovered that the CCA did not have written guidance and had not conducted verification sampling of food contact surfaces (FCS) or the environment as stated in the above mentioned FSIS notification. The lack of ongoing CCA verification sampling of FCS and environment where post-lethality-exposed RTE products are handled established the fact that the CCA is not being consistent with FSIS' RTE equivalence criteria.

The CCA's Coordination Office of Laboratory Support (CGAL) conducts semi-annual audits of the one government and four private microbiology laboratories that conduct analysis of products destined for export to the United States. The audits focus on application of approved FSIS Microbiology Laboratory Guidebook (MLG) methods: calibration of equipment; internal audits; traceability of samples and sample analysis; test kits; ISO 17025 requirements; and verification of corrective actions for previous findings. The CGAL applies a standard procedure to conduct its audit as noted on the CCA's Laboratory Audit Form, *"Plano de auditoria,"* which requires verification of such items as audit scope, facility maintenance, traceability of data, quality manual and procedures, testing methodology (MLG from FSIS), training, and equipment calibration. The FSIS auditor found no concerns after reviewing seven recent CGAL semi-annual laboratory audit reports:

- SFDK Microbiology Laboratory Semi-Annual Audit Reports, April 18-19, 2012, and August 8-9, 2012. A private laboratory located in Sao Paulo.
- LAPOA Microbiology Laboratory Semi-Annual Audit Report, April 16-17, 2012. A private laboratory located in Varzea Grande.
- Lanagro Microbiology Laboratory Semi-Annual Audit Reports, April 16, 2012, and October 8, 2012. A government laboratory located in Pedro-Leopoldo.
- Cerelab Microbiology Laboratory Semi-Annual Audit Reports, May 23, 2011, and Oct 23, 2011. A private laboratory located in Sao Paulo.

At this time because of APHIS' restriction of Foot and Mouth Disease, Brazil is not allowed to export raw beef to the United States. If changes in Brazil's disease status permit export of raw beef, FSIS expects that the CCA develop an equivalent *E. coli* O157:H7 control program before exporting begins.

FSIS concludes that based on the results of the overall microbiological component assessment, the CCA continues to meet the core equivalence requirements for this component. However, FSIS finds that the CCA operates at an adequate level of performance because the CCA's ongoing RTE verification sampling was not fully implemented in accordance with FSIS' RTE equivalence criteria. FSIS expects that the CCA adhere to equivalence criteria and provide documentation describing the change in the CCA verification sampling to ensure that the FSIS standards are being met.

X. CONCLUSIONS AND NEXT STEPS

In conclusion, the CCA meets the core criteria for all six equivalence components; however, the CCA's government oversight needs improvement. Furthermore, the post-audit POE results highlight problems with Brazil's Chemical Residue Control Program that need explicit corrective actions both in the establishment operation and in inspection design. FSIS needs a response from Brazil within 60 days to support Brazil's ability to effectively verify that establishments will conduct a hazard analysis, implement controls, and oversee controls. It also needs to establish that its inspection will continually evaluate establishments to prevent future Ivermectin violations. Until Brazil has satisfactorily addressed these issues, FSIS will not accept Brazil's certification of any new establishment as eligible to export to the United States.

The audit findings were conveyed by the FSIS auditor to the DIPOA inspection officials at an exit meeting on March 14, 2013, in Brasilia. The CCA understood and accepted the need to address these findings to maintain its equivalence:

- The CCA did not provide a standard guideline/circular to its inspection personnel concerning the definition of SRM in cattle in accordance with FSIS' requirements cited in 9 CFR 310.22, resulting in inconsistent implementation of the SRM requirements throughout the system;
- The CCA's RTE verification sampling program did not include on-going verification sampling of food contact surfaces (FCS) and environmental (non-food contact surfaces) in accordance with FSIS' equivalence criteria for *Lm* control in RTE products;
- The CCA's inspection personnel did not fully enforce its basic and ongoing HACCP requirements concerning the contents of HACCP plan and recordkeeping requirements in five audited establishments;
- The CCA's inspection personnel conducted its periodic supervisory reviews at a lower than intended bimonthly frequency in the two swine establishments audited; and
- The CCA's inspection personnel did not fully enforce the CCA's sanitation requirements to prevent cross-contamination of bovine carcasses on the rail-out loop in one slaughter establishment.

The CCA has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term prevention of recurrence of these weaknesses. After receipt and review of the CCA's response, FSIS will further evaluate the effectiveness of the corrective actions through its ongoing equivalence verification methodology.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: The CCA's response to the Draft Final Audit Report (when it becomes available)

Attachment A: Individual Foreign Establishment Audit Checklist

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
JBS S/A Lins, SP	02/20/2013	SIF 337	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[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	
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	
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. SRM control	X
59.	

60. Observation of the Establishment SIF 337: Beef Slaughter/Cutting/Processing

Brazil's Circular No 463/DCI/DIPOA dated August 4, 2004, "Materials of specified hazard for Bovine Spongiform Encephalopathy (BSE) and other requirements of the legislation of the United States," defines the specified risk materials (SRM) from cattle as (1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age or older, (2) the tonsils and the distal ileum of all cattle. This definition is consistent with 9 CFR 310.22 definition of SRM.

Brazil's Memo Circular CGI/DIPOA No 001/2007 dated January 23, 2007, "Guidelines for removal, segregation and disposal of SRM," only defines brain, eyes, spinal cord, tonsils, and distal ileum as SRM for all animals. This Circular did not mention skull, trigeminal ganglia, vertebral column, and dorsal root ganglia as SRM in bovine. This definition is not consistent with 9 CFR 310.22 definition of SRM.

58/51: The CCA did not provide a standard guideline/circular to its inspection system concerning definition of SRM in cattle in accordance with the U.S. requirements cited in 9 CFR 310.22. As a result, the bovine slaughter establishment SIF 337:

- has adopted the latest circular (Memo Circular No 001/2007) definition of SRMs in its written SRM control programs.
- has written procedures for the removal, segregation, and disposal of brain, eyes, spinal cord, tonsils, and distal ileum as SRM materials.
- has maintained daily records sufficient to document the implementation and monitoring of procedures for the removal, segregation, and disposition of brain, eyes, spinal cord, tonsils, and distal ileum.
- has handled all cattle as though they were 30 months of age or older.
- has not either had written procedures for SRM control programs or maintained daily records to document the implementation and monitoring of procedures for the removal, segregation, and disposition of skull, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia in their written SRM control programs.

22/51: The establishment's HACCP verification records (record review and direct observation components) for zero tolerance Critical Control Point (CCP) did not include the time for each entry. [9 CFR § 417.5, and 417.8]

10/51: The establishment has elected to provide a rail-out loop to rail-out suspect bovine carcasses as the result of contaminated or pathological issues for reexamination and further trimming before positioning back on the main line. During the on-site tour of this establishment, the FSIS auditor observed that five bovine carcasses that were awaiting for further examination and trimming were in direct contact with each other. The FSIS auditor and Brazil's inspection service agreed that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of these carcasses. [9 CFR part 416.14 and 416.17]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	2-20-2013

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
Seara Alimentos S/A 155 AV. Paludo Seara, Santa Catarina	03/06/ 2013	SIF 490	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[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 SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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	X
58.	
59.	

60. Observation of the Establishment SIF 490: Swine Slaughter/Cutting/Processing

This establishment is a swine slaughter/cutting/processing (post-lethality exposed ready-to-eat products) facility that has not exported any products to the U.S. since its approval in January 2012.

57: The CCA has not followed its established supervisory reviews frequency (bi-monthly) at this establishment. The CCA conducted one supervisory review (dated December 15, 2012) at this establishment since its approval in January 2012.

51. Equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat (RTE) products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of inspection documents at the CCA headquarters in Brasilia, the Santa Catarina State office, and swine establishment (SIF # 490) in-plant inspection's record revealed that the CCA had not conducted verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment at this establishment in order to verify the effectiveness of establishment's RTE control measures. This is not consistent with the RTE equivalence criteria established by FSIS.

22/51: The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel [9 CFR part 417.5(a) (3) and 417.8].

15/51: The returned product was not included in the establishment's flow chart and hazard analysis [9 CFR part 417.2 and 417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Nader Memarian	Nader Memarian 3-6-2013

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
Marfrig Alimentos S/A Promissao, SP	02/19/2013	SIF 3712	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[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	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. SRM control	X
59.	

60. Observation of the Establishment SIF 3712: Beef Slaughter/Cutting

Brazil's Circular No 463/DCI/DIPOA dated August 4, 2004, "Materials of specified hazard for Bovine Spongiform Encephalopathy (BSE) and other requirements of the legislation of the United States," defines the specified risk materials (SRM) from cattle as (1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age or older, (2) the tonsils and the distal ileum of all cattle. This definition is consistent with 9 CFR 310.22 definition of SRM.

Brazil's Memo Circular CGI/DIPOA No 001/2007 dated January 23, 2007, "Guidelines for removal, segregation and disposal of SRM," only defines brain, eyes, spinal cord, tonsils, and distal ileum as SRM for all animals. This Circular did not mention skull, trigeminal ganglia, vertebral column, and dorsal root ganglia as SRM in bovine. This definition is not consistent with 9 CFR 310.22 definition of SRM.

58/51: The CCA did not provide a standard guideline/circular to its inspection system concerning definition of SRM in cattle in accordance with the U.S. requirements cited in 9 CFR 310.22. As a result, the bovine slaughter establishment SIF 3712:

- has adopted the latest circular (Memo Circular No 001/2007) definition of SRMs in its written SRM control programs.
- has written procedures for the removal, segregation, and disposal of brain, eyes, spinal cord, tonsils, and distal ileum as SRM materials.
- has maintained daily records sufficient to document the implementation and monitoring of procedures for the removal, segregation, and disposition of brain, eyes, spinal cord, tonsils, and distal ileum.
- has handled all cattle as if they were 30 months of age or older.
- has not either had written procedures for SRM control programs or maintained daily records to document the implementation and monitoring of procedures for the removal, segregation, and disposition of skull, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia in their written SRM control programs.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	2-19-2013

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
Beef Snacks do Brazil Santo Antonio da Posse, Sao Paulo	03/08/ 2013	SIF 1690	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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 SIF 1690: Beef Processing

51. Equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat (RTE) products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of in-plant inspection's records revealed that the CCA has conducted verification sampling of post-lethality exposed RTE finished products every other month. However, the CCA had not conducted any food contact surfaces or the environment official verification testing at this establishment. This is not consistent with the RTE equivalence criteria established by FSIS.

22/51: The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel [9 CFR part 417.5(a) (3) and 417.8].

15/51: The returned product was not included in the establishment's flow chart and hazard analysis [9 CFR part 417.2 and 417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Nader Memarian	Nader Memarian 3-8-2013

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
Cooperativa Central Oeste Catarinese Chapeco, Santa Catarina	03/05/ 2013	SIF 3548	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
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	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	X
58.	
59.	

60. Observation of the Establishment SIF 3548: Swine Slaughter/Cutting/Processing

This establishment is a swine slaughter/cutting/processing (post-lethality exposed ready-to-eat products) facility that has not exported any products to the U.S. since its approval in January 2012.

57: The CCA has not followed its established supervisory reviews frequency (bi-monthly) at this establishment. The CCA conducted one supervisory review (dated December 12, 2012) at this establishment since its approval in January 2012.

51. Equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat (RTE) products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of inspection documents at the CCA headquarters in Brasilia, the Santa Catarina State office, and swine establishment (SIF # 3548) in-plant inspection's record revealed that the CCA had not conducted verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment at this establishment in order to verify the effectiveness of establishment's RTE control measures. This is not consistent with the RTE equivalence criteria established by FSIS.

15/51: The returned product was not included in the establishment's flow chart and hazard analysis [9 CFR part 417.2 and 417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Nader Memarian	Nader Memarian 3-5-2013

Attachment B: The CCA's response to the Draft Final Audit Report

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health - SDA
Department of Inspection of Animal Products - DIPOA

Letter no. 100/2014/GAB/DIPOA/SDA

Brasília, March 25th, 2014.

Dear Sir,
SHAUKAT H. SYED
Director – International Audit Staff
Office of Investigation, Enforcement and Audit
FSIS-USDA – Washington - United States

Reference: ***Brazil. Draft Final Audit Report*** **– Comments from DIPOA/SDA/MAPA.**

Dear Mr. Syed,

1. I would like to greet you and express the respect I have for the *Food Safety and Inspection Service – United States Department of Agriculture* and make reference to the *Draft Final Audit Report*, dated January 7, 2014, about the Preliminary Audit Report of the Brazilian Meat Inspection System, which took place from February 18 through March 14, 2013.

2. The Department of Inspection of Animal Products – DIPOA, under the Secretariat of Animal and Plant Health of the Ministry of Agriculture, Livestock and Food Supply in Brazil – SDA/MAPA, hereby submits its comments to the aforementioned *Draft Final Audit Report*.

Mr. Syed, please receive my wishes of esteem and consideration.

Best regards,

Leandro Diamantino Feijó
Deputy Director of DIPOA/SDA/MAPA

Esplanada dos Ministérios, Bloco D – Anexo B – Sala 406 – 70.043-900 – Brasília/DF – Tel: (+5561) 3218-2339 Fax: (+5561) 3224-3995

Ministry of Agriculture, Livestock and Food Supply
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products

COMMENTS

to the Draft Final Audit Report of the FSIS-USDA
(which took place from Feb. 18 through Mar. 14, 2013)

2014

Esplanada dos Ministérios, Bloco D – Anexo B – Sala 406 – 70.043-900 – Brasília/DF – Tel: (+5561) 3218-2339 Fax: (+5561) 3224-3995

INTRODUCTION

The FSIS-USDA held an audit in Brazil from February 18 through March 14, 2013 to verify the equivalence of the Brazilian meat inspection system to the United States system, that is, producing safe, whole and non-adulterated and properly labeled foods.

The FSIS-USDA audit was outlined to establish the equivalence of the Brazilian Meat Inspection System in six main components: 1) *Government Oversight*; 2) *Statutory Authority and Food-Safety Regulations*; 3) *Sanitation*; 4) *Hazard Analysis and Critical Control Points (HACCP) Systems*; 5) *Chemical Residue Control Programs*; and 6) *Microbiological Testing Programs*. In addition to these components, the audit also emphasized the verification of corrective actions related to the audit findings of the 2010 audit (inadequate control of chemical residues, particularly ivermectin; ineffectiveness of the product recall process), effectiveness of actions taken by the Central Competent Authority based on the recent case of BSE, and lastly, verify the control and activities of the Central Competent Authority in relation to the inspection in swine slaughter establishments recently approved for export to the United States of America.

The main audit findings, in summary, were as follows:

a) DIPOA did not submit a Circular letter at SIGSIF to define the Specific Risk Material (SRM), according to the requirements set forth by the FSIS (9 CFR 310.22);

b) The official verification of the manufacturing process of ready to eat foods did not include samples of contact surfaces and the environment, that is, does not comply with the equivalence criteria to control and prevent *Listeria monocytogenes* in ready to eat (RTE) foods according to the FSIS;

c) Official inspection personnel did not thoroughly verify the content in the HACCP plans and in the monitoring records of five establishments audited;

d) Official inspection personnel carried out periodical supervisions in a smaller frequency than the bimonthly frequency in the swine slaughter establishments visited;

e) Official inspection personnel did not thoroughly verify the sanitation requirements in order to prevent cross-contamination of bovine carcasses in one of the bovine slaughter establishments visited.

The FSIS-USDA audit indicated that the Brazilian Inspection System is performing in an "adequate" level in maintaining its equivalence. However, the FSIS-USDA requires answers from DIPOA regarding the effective implementation of the Circulars to assess the hazard analysis, monitoring, verification, corrective actions, record keeping, criteria and audit of the HACCP plans related to ivermectin controls, in order to avoid new future violations of ivermectin residues in bovine meat.

BRAZIL UPDATED INSPECTION GUIDELINES

Official Response to Audit Results by USDA-FSIS

The Central Competent Authority (CCA) understood and accepted the need to address the following findings to maintain its equivalence.

I.) The CCA did not provide a standard guideline/circular to its inspection personnel concerning the definition of Specified Risk Materials (SRM) in cattle in accordance with FSIS' requirements cited in 9 CFR 310.22, resulting in inconsistent implementation of the SRM requirements throughout the system.

Establishments approved for export to the USA have reviewed their self-control programs in order to comply with Circular nº 463/2004/DCI/DIPOA. They have included the skull, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia as Specific Risk Material, controlling the handling, segregation and disposition of these products. According to the aforementioned Circular, all SRMs are disposed of as inedible products.

II.) The CCA's Ready to Eat (RTE) verification program did not include on-going verification sampling of food contact surfaces (FCS) and environmental (non-food contact surfaces) in accordance with FSIS' equivalence criteria for control and prevention of Listeria monocytogenes (Lm) in RTE products.

Brazil required establishments to provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria monocytogenes* (*Lm*) and/or of an indicator organism. In addition, establishments were required to identify the size and location of the sites that will be sampled. In order for an establishment to ensure that food contact surfaces are sanitary and free of *Lm*, all possible food contact surfaces should be identified for sampling. If the establishment does not identify all possible food contact surfaces for sampling, they would be expected to provide supporting documentation to show why product or food contact surfaces would likely not be contaminated. The new DIPOA guidance was published in the Circular Memorandum DICS/CGI/DIPOA n°. 019/2014 (attached).

III.) The CCA's inspection personnel did not fully enforce HACCP requirements concerning the contents of HACCP plan and record keeping requirements in five audited establishments.

Brazil will verify that either a copy of the HACCP verification results or the actual piece of paper or notepad identifying the HACCP verification result and have it available to review if necessary. In addition, the plan should provide for the record keeping system being used for monitoring. The record would need to be a transcription of the information on the paper or notepad by the same or different person which includes the time, date, and initials or name of the person that recorded the original data onto the piece of paper or notepad. DIPOA published on SIGSIF a new guidance for Official Inspection personnel training in HACCP through Memorandum Nº 120/2014/CGPE/DIPOA (attached).

IV.) The CCA's inspection personnel conducted its periodic supervisory reviews at a lower than intended bimonthly frequency in the two swine establishments audited.

The CCA will make sure that reviews will be maintained as scheduled. Each review will be comprehensive and an analysis of all information. A written Report of Findings and Recommendations will be prepared and disseminated. SIPOA/Santa Catarina has already scheduled the 2014 supervisions at the swine slaughter establishments approved for export to the United States to be carried out in a bimonthly frequency.

V.) The CCA's inspection personnel did not fully enforce the CCA's sanitation requirements to prevent cross-contamination of bovine carcasses on the rail-out loop in one slaughter establishment.

Brazil will conduct, verify, and document that the Inspection Training course covers the essential inspection verification tasks including the prevention of cross-contamination.

CHEMICAL RESIDUE CONTROLS

In relation to the FSIS-USDA 2010 audit findings related to the corrective actions taken by DIPOA about the inadequate chemical residue control process, especially ivermectin, please see below this Department comments about the implementation and/or improvement of actions to provide guarantees to the health officials of the United States (FSIS-USDA):

1. DIPOA established that SIPOA/SISA/SIFISA, according to Memorandum no. 110/2014/CGPE/DIPOA (attached), dated February 20, 2014, must perform Supervisions in all approved establishments for export to the United States of America, including instructions and report template that focus on the companies HACCP plan, seeking to mitigate chemical hazards in relation to the occurrence

of ivermectin in raw material and heat processed meat products exported to the United States. Additionally DIPOA reports that supervisions in establishments have already started in all establishments authorized to export to the United States;

2. DIPOA established that SIPOA/SISA/SIFISA, according to Memorandum no. 120/2014/CGPE/DIPOA (attached), dated February 21, 2014, must hold training courses about HACCP for all VMOs that perform activities in establishments approved for export to the United States of America, focused on record keeping (weaknesses) included in the report of the last mission submitted by the FSIS/USDA;

3. DIPOA initiated discussions about the PNCRC/MAPA Exploratory Subprogram for ivermectin analysis in bovine muscle, which was implemented at the end of 2010 to comply with the agreement entered into with the FSIS-USDA. The sample collection amount will remain at 230 samples/year (2014) and can be adjusted on the future if technically necessary. It is essential to make clear that only those establishments authorized for export to the U.S. are participating in this sampling in muscle, taking into account the MRL of 10 ppb issued by FSIS/USDA authorities;

4. DIPOA is in process to update the Official Letter Circular no. 21/2010 and Circular no. 196/2010/CHC/CGPE/DIPOA, considering the specificities of the self-controls carried out by the different industries to control ivermectin in order to comply with US health requirements, where each industry, at its sole discretion, will choose the target tissue (muscle and/or liver) to carry out their self-controls for the presence of ivermectin.

AVERMECTIN CHEMICAL RESIDUE CONTROL IN BRAZILIAN SLAUGHTERHOUSES

INTRODUCTION

DIPOA presents, in general, the updated controls adopted by establishments authorized to trade with the U.S. regarding the detection of ivermectin residues in beef.

OBJECTIVE

The Chemical Residue Control Program (Avermectins) includes the instructions, assessment and selection of rural properties, guidelines to generate and/or receive raw material, analytical sampling during the production chain and taking corrective actions in case of deviations.

RAW MATERIAL SUPPLY CRITERIA

In order to comply with the residues program, slaughterhouses must:

✓ **Approve raw material suppliers:**

- Audit suppliers;
- Provide guidance on how to use and administer veterinary medicine;
- Receive a Letter of Guarantee from Farmer, which certifies that the withdrawal periods for the veterinary medicines administered have been met.

Corrective Action: Properties that have avermectin violations must go through a new inspection.

CONTROL STAGES

✓ **Receiving animals:**

- Verify supplier approval status;
- Check if there is a Letter of Guarantee from the farmer and if it is filled out correctly (CCP 1Q);

Corrective Action: Non-compliance with the subitems under receiving animals, implies in segregating the lot of animals and they must be destined to other markets.

✓ **Slaughter:**

- Collect samples during slaughter for the avermectin analysis;
- Samples collected during slaughter must be analyzed in the company's own laboratories by the immunoenzymatic (Elisa - Enzyme-Linked Immunosorbent Assay) and/or High Performance Liquid Chromatography (HPLC) or UPLC (Ultra performance liquid chromatography techniques;
- Based on the analytical results obtained, and according to the limits established by markets, raw material will be released or segregated.

Corrective Action: In case violations are found in the slaughter lots, the property will be blocked and await new inspection in order to resume raw material supply.

✓ **Production of heat processed products:**

- All heat processed products destined for the USA, must be produced from raw material and approved;

Corrective Action: Violated lots will be segregated and not exported to the USA.

✓ **Official verification**

- The samples will be collected and sent to the Ministry of Agriculture accredited labs for all lots produced.
- Lots will be approved based on the result of the MRL of each importing country.

IMPROVEMENT ACTIONS IMPLEMENTED AFTER THE FSIS/USDA MISSION IN 2013

- ✓ Increased sampling of lots in Brazilian states where the incidence of violations is higher.
- ✓ Review of the chemical contaminants risk analysis in bovines according to a prevalence and toxicity level analysis established by MAPA in the National Program for Residue and Contaminants Control (PNCRC) and other regulatory agencies (FDA/FAO/OIE/ANVISA).
- ✓ According to the Residue Control plan, analyses are made on raw material and finished goods with a variable frequency considering the risk established.
- ✓ The number of samples was increased in heat processed products.

Scientific studies were carried out through a partnership with Academic Institutions aiming at learning how the ivermectin residues behave in the animal's body, which tissues have higher concentration of residue content, which tissues take longer to deplete the drug and which tissues should be avoided in the ingredients of processed goods.

Department of Inspection of Livestock Inputs – DFIP/SDA/MAPA

Comments to the Draft Final Audit Report

1. SDA will start a working group composed by technical representatives of the MAPA, ABIEC, manufacturers of veterinary medicinal products and universities, to develop a model of scientific experiment to evaluate efficacy and safety of use of long-acting avermectin veterinary products, and the influence of the use of these products on the final composition of products of animal origin. This study will be conducted in partnership with MAPA, ABIEC and Brazilian manufacturer of veterinary products. If the results of this experiment show any evidence that the use of long-acting avermectin cause negative influence of the quality of food by animal origin, SDA/MAPA will promote the forbidden of the use of this kind of product in Brazil.

2. Inclusion of products containing long-acting avermectin in a list of products under controlled sale. For that we need to update the rule of Order nº. 25/2012, which deals with the theme. The SDA informs that the estimated deadline for the official publication of the new guidance regarding this issue is estimated at 120 days (until July, 2014).

3. Start of official program with fiscal analysis of injectable products containing ivermectin in its composition. This evaluation will be conducted in LANAGRO/SP located in Campinas/SP. The ability of initial tests will be 20 samples per month, and the deadline for the beginning of the official harvest is estimated at 60 days (until June 2, 2014).

General Coordination of Laboratorial Support – CGAL/SDA/MAPA

Comments to the Draft Final Audit Report

1. **Regarding the analysis of ivermectin:** The laboratories of the National Network of Agricultural Laboratories are currently fit to perform analysis of ivermectin in bovine muscle by LC-MS/MS so as to meet the limits proposed by the USA (10 ppb).

2. **Regarding the analysis of level of ivermectin in veterinary products:** The National Agricultural Laboratory of São Paulo (Lanagro, SP) is currently structured and fit to perform analysis of content of ivermectin in veterinary products as part of the inspection activities, having, for such purposes, a validated method and other laboratory procedures, awaiting only the completion of the sample collection schedule by the Department of Inspection of Livestock Inputs – DFIP/SDA/MAPA.

3. **Regarding the MRLs for processed products:** Antiparasitics belonging to the avermectin class, particularly ivermectin, have been monitored by the National Plan for Residue Control (NRCP) since 1998, in cow's milk and liver matrices. In 2010, a special program of surveillance in bovine muscle target matrix was introduced by the Brazil's Ministry of Agriculture to control levels of avermectin residues in raw materials for the production of processed meat products, because samples exported to the United States were identified as non-compliant by the laboratory-based monitoring system in that country. The legal limit established for ivermectin residue in this special sanitary surveillance program is the same limit applied in the USA (10 mg kg - 1). Once implemented, the sanitary surveillance program in muscle identified a profile of occurrence of residues different from that which resulted from notifications of non-compliant processed products exported to the United States. Since fat is added to the meat-based processed foods during processing, and considering that the added fat may lead to increased levels of ivermectin because it is a lipophilic drug, a new approach for identifying safe levels of this residue in processed meat is required, going far beyond simply extrapolating – to processed products – a limit that was originally established only for muscle. To assure a reasonable MRL value for processed meat-based products and to maintain quality and safety for consumers, it is necessary to consider other

variables in this new approach, such as pharmacokinetic and toxicological data and processing factors in defining MRL. The latest evaluation for ivermectin conducted by the *Codex Alimentarius* Commission established an acceptable daily intake (ADI) of 1 mg/kg body weight, and no MRL has been established for muscle. In 2004, the European Commission redefined the ADI to 10 mg per kilo of body weight per day (600 µg per person per day) and considered that a safety factor of 50 is suitable for the establishment of an ADI based on the NOEL of 0.5 mg per kilo of body weight per day. To calculate the estimates of dietary exposure, the FAO manual on the submission and evaluation of pesticide residue data for estimating maximum residue levels in food and animal feed (2nd edition, Rome, 2002 http://www.fao.org/ag/agp/agpp/Pesticid/JMPR/Download/faom2002.doc) sets out specific procedures to calculate the "Supervised Trials Median Residue In Processed Commodity (STMR-P)" as a way to represent the median level of residue in processed food commodities for estimating chronic dietary exposure and risk. Additionally, Technical Reports such as the "STANDARD 1.4.2" of Food Standards Australia New Zealand, demonstrate a calculation of MRL based on a weighting with regard to mixed or processed foods that contain ingredients. In light of current observations, we believe that, at this time, the adoption of an MRL of 30 mg kg -1 for ivermectin in processed meat-based products may be an alternative to the limit of the ivermectin residue monitoring program, without compromising safety aspects in any way. Furthermore, a more comprehensive study on processing factors can still be considered to assess the level of ivermectin residues in processed meat products, and to establish the reasonableness of the proposed MRLs.

These informations were delivered to U.S. Health Authorities in the last Agricultural Advisory Committee Meeting Brazil-U.S., held at the end of the year 2013, and that statement is up waiting for scheduling USDA-FSIS technical meeting to discuss this issue.

Below are the Action Plans and Corrective/Preventive Actions of the establishments audited by FSIS/USDA.

DIPOA would like to thank the opportunity to receive the comments contained in the Draft Final Audit Report, which will assist in the improvement of the Official Control System and also in self-control of enterprises.

We remain at your entire disposal to clarify any doubts regarding to the Draft Final Audit Report.

1) SIF 337

ACTION PLAN FOR CORRECTION OF NONCONFORMITIES POINTED DURING THE AMERICAN MISSION IN 20/02/2013, BY DR. NADER MEMARIAN				
ITEMS	*NONCONFORMITIES*	*CORRECTIVE ACTIONS*	*PREVENTIVE ACTIONS*	*TIME TO PERFORM*
10/51	***Slaugther room (DIF):*** *The establishment has elected to provide a rail-out loop to rail-out suspect bovine carcasses as the result of contaminated or pathological issues for reexamination and further trimming before positioning back on the main line. During the on-site tour of this establishment, the FSIS auditor observed that five bovine carcasses that were awaiting for further examination and trimming were in direct contact with each other. The FSIS auditor and Brazil´s inspection service agreed that the establishment´s rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of these carcasses. [9 CFR part 416.14 and 416.17]*	*- In Timeout for bathroom, the platform was cleaned, performed as recommended for product contact surfaces.* *- It was determined that the employee responsible for placing the traceability label, positioned before the tail withdrawal platform, orient the position of the carcass so that the tail is facing the opposite direction of the platform.*	*- Review the Operational SSOP Plan from the slaughter, inserting the platform from the toiletries area as surface with contact with the product (page 80 of the reviewed plan DGU-337/1-GQU-002B/02 - Annex 1).* *- Orientate employees involved in cleaning operation (training registered Annex 2).* *- Adapt the platform, reducing the size of it, to avoid contact of the half carcass with the parapet (Annex 03).* *- Install the siren at the DIF department to stop the slaughter line when necessary (Annex 4).*	**05/03/2013** **30/03/2013** **20/02/2013** **20/02/2013**

22/51	*The establishment's HACCP verification records (record review and direct observation components) for zero tolerance Critical Control Point (CCP) did not include the time for each entry. [9 CFR § 417.5, and 417.8]*	*Document (RGQ-337/1-GQU-016) reviewed and added time and signing in the record in each start and end of the evaluation of the front and hindquarter.*	*- Train the employees responsible for monitoring CCP 1B on correct completion of the new worksheet (Annex 05).*	**02/07/2013**
58/51	*Establishment SIF 337 has not either had written procedures for SRM control programs or maintained daily records to document the implementation and monitoring of procedures for the removal, segregation, and disposition of skull, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia in their written SRM control programs.*	*Company procedures were revised by inserting the definition of Specific Risk Material information contained in Circular No. 463/2004/DCI/DIPOA, which is based on FSIS Directive 6100.4 published by FSIS/USDA.*	*- Daily control records for SRM regarding its removal, segregation and disposal are maintained (Annex 06).*	Document DGU-337/1-GQU-003. Last revision on **19/06/2013**

2) SIF 490

Official Service Guideline for SIF 490 for inspections addressing requirements considered to be non-conformities in the "Foreign Establishment Audit Checklist":

The establishment has been suspended by CCA since 09/12/2013, in accordance with Circular no. 836/2013/CGPE/DIPOA (attached), due to reincidence of non compliances detected during FSIS-USDA Audit (06/03/2013), DIPOA´s audit (from 02 to 04th of April, 2013) and SIPOA-SC routine supervision (from 10 to 13th of June, 2013), never having obtained an International Sanitary Certificate from SIGSIF (General SIF Information System), and has not yet exported any product to the United States.

The establishment acknowledged the SIF of its awareness of the "Foreign Establishment Audit Checklist" report on 20/02/2014, and of its responsibility to assess and act upon the noncompliance issues addressed therein.

For official verification of the actions adopted by the establishment, SIPOA-SC notified SIF 490 of the enforcement actions below:

Item 51: The SIF informed the establishment about Circular Memorandum nº. 19/2014 on 17/03/2014, and that it would need to adopt the Official Verification procedures of the results of the testing for *Listeria monocytogenes* on the contact surfaces of ready-to-eat products to support the sanitary certification of these products.

Item 15: Contents of the list of food safety hazards, CCPs [Critical Control Points], CLs [Critical Limits], procedures, corrective actions/**Item 51**: enforcement

The SIF must establish a reasonable deadline so that the products returned by the recall system of the company may be included in the process flow diagram and may undergo a hazard and critical control point analysis. Reprocessing of the recalled products will not be authorized until this analysis is included.

In addition, we advise that finished products returned from their initial destinations, for issues other than recall, must also be considered in the flowchart and in the hazard and critical control point analysis.

Item 22: Document registration: HACPP plan described, monitoring of CCPs, dates and times of specific incidents. /**Item 51**: enforcement

Considering the findings, the SIF must define the requirements for a review of the HACPP monitoring records in order to identify and correct other deficiencies of the same nature. The SIF must improve the accuracy of its document audits and increase the number of documents included in the monthly audit sample, until such time as the Official Service verifies that there are no more incidents of this nature.

Item 57: "*Monthly Review*" The SIPOA-SC understands that while the sanitary certification of products for export to the US originating from the establishment under SIF490 is suspended, a schedule of biannual supervision will be maintained. As soon as the company notifies the local SIF that it has taken action to comply with the specific requirements and formally declares itself eligible to receive a specific supervision to lift the suspension and to be reinstated to certification status, SIPOA will include it in the cycle of bimonthly state supervisions applied to establishments considered eligible for certification for export to the US.

3) SIF 1690

Action Plan

Establishment and Localization: Beef Snacks do Brazil - Actual name: Meat Snack Partners do Brazil – Santo Antonio de Posse
Establishment No. SIF 1690 **Audit Date** 03/08/2013 **Country** Brazil
Auditor Dr. Nader Memarian

ITENS	NON COMPLIANCE	(A) CORRECTIVES ACTIONS	(B) PREVENTIVES ACTIONS	DEADLINE	VERIFICATIONS (Federal Inspection)
15 -Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	The establishment's HACCP verification records for review of records component did not document the time or the results of the ongoing verification activities conducted by the establishment's personnel [9CRF part 417.5(a) (3) and 417.8]	1) Changing the HACCP plan including the description of the item check daily record, date, time and result (compliant and non-compliant). 2) Changing the plan of Biological monitoring of CCP 1 and CCP 2 Physical (Plan-1690-GQ-028 and Plan-1690-GQ - 031) including the date, time and result (compliant and non-compliant).	1 and 2) Review by HACCP team as the company plan to meet items (9 CFR part 417.5(a) (3) and 417.8)	A 1) 02/26/2014* 2) 03/08/2013 B) 02/26/2014*	A (1 e 2) e B Realizados em 28/02/14 Paulo M. Paiva Jr. Fiscal Federal Agropecuário Médico Veterinário-CRMV-SP 7370
22- Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	The returned product was not included in the establishment's flow chart and hazard analysis [9CRF part 417.2 and 417.8]	Changing the HACCP plan including the returned product in the flow chart and hazard analysis.	Review by HACCP team as the company plan to meet items (9 CFR part 417.2 and 417.8)	A) 02/26/2014* B) 02/26/2014*	A Realizar - dos em 28/02/2014 Paulo M. Paiva Jr. Fiscal Federal Agropecuário Médico Veterinário-CRMV-SP 73

*Actions conducted after received the audit report.

José Carlos Xavier
Plant Manager

Jacqueline Citrangulo
Coordinator of Quality Assurance

4) SIF 3548

ACTION PLAN FOR THE RESTRICTIONS AND NON-CONFORMITIES IDENTIFIED BY FSIS-USDA AUDIT – SIF 3548			
Inspection Date	Restriction or non-conformity	Description of corrective/preventative action	Deadline for conclusion
04/03/2013	51. A review of inspection documents at the CCA headquarters in Brasilia, at the Santa Catarina state office, and of the in-plant inspection records at the swine establishment (SIF 3548) revealed that the CCA did not conduct post-lethality verification sampling for RTE product exposure, either of food contact surfaces or of the environment at this establishment in order to verify the effectiveness of the RTE control measures of the establishment. This is not consistent with the equivalency criteria for RTEs established by the FSIS.	Regarding the company plan, a sample collection plan covering points with and without contact with products in the RTE exposure area was prepared and is already included in the Manual of Microbiological Results in accordance with the date cited.	12/04/2013
04/03/2013	15/51 - Returned product was not considered in the flowchart and hazard analysis of the establishment.	The HACCP plan was revised to include the study and hazard analysis of returned product in accordance with the date cited.	22/08/2013

Official Service Guideline for SIF 3548 for inspections addressing requirements considered to be non-conformities in the "Foreign Establishment Audit Checklist":

The establishment is eligible for exportation to the United States, but has not yet shipped any product.

The establishment acknowledged, to the SIF, its awareness of the "Foreign Establishment Audit Checklist" report on 24/02/2014, and of its responsibility to assess and act upon the non-conformities issues addressed therein.

For official verification of the actions adopted by the establishment, SIPOA-SC notified SIF 3548 of the enforcement actions below:

Item 51: The SIF acknowledged its awareness of Circular Memorandum nº 19/2014 on 20/03/2014, and should adopt the official verification procedures of the results of the testing for *Listeria monocytogenes* on the contact surfaces of ready-to-eat products, to support the sanitary certification of these products.

Item 15: Contents of the list of food safety hazards, CCPs [Critical Control Points], CLs [Critical Limits], procedures, corrective actions/**Item 51**: enforcement

The SIF must establish a reasonable deadline so that products returned by the recall system of the company can be included in the process flow diagram and can undergo hazard and critical control point analysis. Reprocessing of recalled products will not be authorized until this analysis is included.

In addition, we advise that finished products returned from their initial destinations, for issues other than recalls, must also be considered in the flowchart and in the hazard and critical control point analysis.

Item 57: "*Monthly Review*" The SIPOA/SC established and submitted a bimonthly oversight schedule to DIPOA, covering all establishments currently eligible for exportation to the US (SIF 140 and SIF 3548), with the first evaluation of the establishment under SIF 3548 already conducted and completed on 27/02/2014.

5) SIF 3712

Correction Action Plan for Non Compliance Report Pointed in the Veterinary Mission FSIS / USDA (Period 02/19/2013 - SIF 3712 - Auditor: Dr. Nader Memarian)			
NONCONFORMITIES	**CORRECTIVE MEASURES**	**PREVENTIVE MEASURES**	**TIME ATTENDANCE**
The definition of Specific Material Risk - SMR programs in self-control company believes the information set forth in Memo Nº. 001/2007/CGI/DIPOA and not the provisions of Circular No. 463/2004/DCI/DIPOA. Note: The actions in relation to ECMs contained in Circular No. 463/2004/DCI/DIPOA and are absent in the Memorandum No. 001/2007/CGI/DIPOA shall be responsible for the regulatory DIPOA / SDA;	The MRE program was revised by inserting the definition of Specific Risk Material information contained in Circular No. 463/2004/DCI/DIPOA based on FSIS Directive 6100.4	There is no preventive measure for Noncompliance pointed.	Corrective Action: 02/19/2013
There was no review of programs of self-control company seeking revaluation of risk after the occurrence of the BSE case in Paraná / BR	Programs of self-control has not been reviewed by the case of BSE occurred in Paraná, Brazil because the country remain as Negligible Risk, as the decision that the OIE adopted Resolution No. 16 in May 2012 and the procedures and controls company continue running and meeting the requirements for this risk.	Program Review and Hazard Analysis Critical Control Points (HACCP), adapting to the Resolution No. 16 May 2012 (adopted by OIE) which considers Brazil as Negligible Risk for BSE.	Preventive action: 03/20/2013

Attachments

Memorandum no. 110/2014/CGPE/DIPOA

Memorandum no. 120/2014/CGPE/DIPOA

Circular Memorandum DICS/CGI/DIPOA no. 019/2014

Circular no. 836/2013/CGPE/DIPOA

Esplanada dos Ministérios, Bloco D – Anexo B – Sala 406 – 70.043-900 – Brasília/DF – Tel: (+5561) 3218-2339 Fax: (+5561) 3224-3995

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products
General Coordination Office for Special Programs

Memorandum Nº 110 /2014/CGPE/DIPOA **Brasília, 20/02/2014.**

From: General Coordinator of Special Programs - CGPE/DIPOA

To: Heads of the SIPOAs, SISAs, SIFISAs.

Subject: Forwarding the model of the inspection report focusing on the assessment of chemical hazards.

Dear Sirs:

We hereby forward, attached herewith, the model of the report for the assessment of review of plans for Hazard Analysis and Critical Control Points (HACCP) for cattle slaughter establishments, focusing on chemical hazards - ivermectin, to be used in the next round of state inspections in establishments licensed to export beef to the United States of America.

As this Office has been receiving signals from the FSIS/USDA that Brazil may receive a new mission to assess the correction of non-compliances identified during the visit held in February/March 2013, already in April 2014, the inspections to be carried out in the second quarter of the current year should occur during March.

The report model was created to assess, in a targeted and detailed manner, whether the methodology adopted by facilities to identify, assess and control chemical hazards within their HACCP plan, meets the objective of assuring that products manufactured at such facilities meet the goals of food safety recommended by Brazilian legislation currently in force, as well as international law, where applicable.

Thus, if the conclusion of the report is that the establishment does not have control of processes for international accreditation or shows evidence of loss of control, the measures set forth in Regulatory Instruction No. 27 of 27/08/2008 shall be applied.

Immediately after completion of the inspection, the reports shall be scanned and sent by the SIPOAs, SISAs and SIFISAs to the email address cch@agricultura.gov.br for analysis and consolidation of the data obtained.

We emphasize that, although the focus of inspections is on the assessment of chemical hazards within the HACCP plan, the establishment's other programs of self-control must also be assessed through the report model established by Circular Letter No. 228/2005/CGPE/DIPOA.

Best regards,

Leandro Diamantino Feljó
Federal Agricultural Inspector
Veterinarian – CRMV/MG 6277
Director of the DIPOA/SDA – Alternate

Esplanada dos Ministérios, Bloco D – Anexo B – Sala 406 – 70.043-900 – Brasília/DF – Tel: (+5561) 3218-2339 Fax: (+5561) 3224-3995

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products
General Coordination Office for Special Programs
Coordination Office of Licensing and Certification

Assessment Report on the Review of the Plan of Hazard Analysis and Critical Control Points (HACCP) of cattle slaughter establishments, focusing on chemical hazards (verified onsite)

Report nº.:

Date of review:

Auditors:

Establishment:

Location:

Purpose: Verification of implementation of the Plan of Hazard Analysis and Critical Control Points (HACCP) in cattle slaughter establishments, focusing on Chemical Hazards.

(1) Does the establishment have a waste control program? **YES** ( ) **NO** ( )

(1a) How did you come to the conclusion of item (1)? Describe what you observed or the programs reviewed. If the answer is **YES**, describe the program.

(2) During Hazard Analysis, did the establishment identify chemical hazards (residues of veterinary products or environmental contaminants) with high or reasonable probability of occurrence? **YES** ( ) **NO** ( )

(2a) If the answer of the previous item was "NO," is there evidence that the establishment, in re-assessment of the Plan, based itself on the validation of the Plan? Did this validation use the monitoring information of the prerequisite program, the results of the PNCRC, and

the monitoring programs of the veterinary services of the countries that import Brazilian products? **YES ( ) NO ( )**

(2b) How did you come to this conclusion? Describe what you observed and the documents reviewed.

(2c) Describe the controls carried out by the establishment and documentation to support the decision that the likelihood of occurrence of these hazards is negligible.

(2d) Describe how the hazards are controlled (in the HACCP Plan, in Good Manufacturing Practices programs, or prerequisite programs)

(3) Are there documents that accompany the animals sent to slaughter and that identify the animals that received any type of veterinary medicine (where, when, and for what purpose)? **YES ( ) NO ( )**

(4) What system of animal identification does the establishment use? Does it use identification applied during postmortem inspection (numbering of the carcass and parts)? Does the system allow traceability back to the producer?

(4a) How did you come to this conclusion? Describe what you observed and cite documents reviewed. Describe the identification system.

(5) In the last 12 months, has the establishment received any notification from the DIPOA or from veterinary services of the importing countries, regarding violations of residue levels? **YES ( ) NO ( )**

(5a) If the answer to item (5) is YES, what actions has the establishment taken to prevent recurrence?

(5b) If the answer is **YES**, does the establishment have a system of notifying the producer, informing it of violations of residue limits of veterinary products? **YES** ( ) **NO** ( )

(5c) If the answer is **YES**, does such notification alert the producer as to the gravity and implications with regard to the marketing of products with high levels of residues of veterinary products? **YES** ( ) **NO** ( )

(5d) If the answer is **YES**, did the establishment provide the DIPOA with the name and address of the vendor? **YES** ( ) **NO** ( )

(6) Does the establishment participate in any voluntary program offered by certification organizations that evaluate residue control programs? **YES** ( ) **NO** ( ) **INFORMATION NOT AVAILABLE** ( )

(7) Final Analysis: Describe the establishment's residue control program. Describe the impact of the establishment's program on the food safety assurance system.

Auditors:

Representatives of the SIF:

Representatives of the Establishment:

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products
General Coordination Office for Special Programs

Memorandum Nº 120/2014/CGPE/DIPOA **Brasília, 21/02/2014.**

From: General Coordinator of Special Programs - CGPE/DIPOA

To: Chiefs of the SIPOAs, SISAs, SIFISAs.

Subject: United States of America. Training. HACCP.

Dear Sir:

The report sent via Circular Letter No. 154/2014/CGPE/DIPOA lists the key deficiencies found by the FSIS/USDA mission when visiting Brazil in February/March 2013.

Among these deficiencies, flaws were identified in the procedures adopted by the Official Inspection Service for verifying the plans of Hazard Analysis and Critical Control Points developed by establishments. The items indicated as deficient were the verification of the records prepared by the establishments and verification of production flowchart.

Thus, considering the findings of the report as well as the recommendations contained therein, and the need to take the necessary corrective and preventive actions vis-à-vis the foregoing, this Department has determined that the SIPOAs, SISAs and SIFISAs that have establishments qualified to export meat to the United States of America hold technical meetings that must be attended not only by those in charge of qualified establishments, but also the supervisors who carry out bimonthly supervision of said establishments.

The topic of these meetings, which should occur in the first half of 2014, shall be refresher training of the inspectors as to the procedures to be employed for the assessment of HACCP plans, based on the current legislation on this subject.

If there is need for financial support for holding the meetings, the DIPOA should be notified so that the necessary resources can be made available.

Best regards,

Leandro Diamantino Feijó
Federal Agricultural Inspector
Veterinarian CRMV/MG 6277
Director of DIPOA/SDA – Alternate

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products
General Coordination of Inspection

Circular Memorandum DICS/CGI/DIPOA N°. 019/2014 **Date: 14/03/2014**

From : DICS/CGI/DIPOA
To : SIPOA/SISA/SIFISAs
Subject : Requisites for export to the USA – Microbiological Controls (EI 15) for Ready To Eat foods

Dear Sirs:

Considering the results of the Food Safety and Inspection Service (FSIS) mission, concluded on March 14, 2013, we believe that additional measures must be implemented to control *Listeria monocytogenes* in post-processing ready-to-eat products. Thus, in addition to verification of samples of the food products *per se*, we believe that routine verification of the surfaces having direct and indirect contact with the surfaces of such products should be practiced.

Accordingly, we refer to the verification of the sentinel program for *Listeria* sp., as well as a minimum bimonthly frequency for analyses on the final product, which are described in Attachment I of Circular Letter No. 175/2005/CGPE/DIPOA and Circular Letter No. 904/2011/CGPE/DIPOA.

We know that *Listeria* sp. is capable of forming colonies on process equipment, particularly in areas with maintenance deficiencies or that are difficult to access for cleaning. The implementation of an equipment maintenance program is an efficient preventive measure aimed at controlling *Listeria monocytogenes.* Thus, inspection of equipment allows for an evaluation regarding the application and effectiveness of the maintenance program.

The establishment must have a sentinel program for *Listeria* sp. aimed at the area used for handling finished products, as a tool for verifying the SSOP in this environment. Prior to choosing the sampled surfaces, the establishment must identify and separately list the surfaces that come into contact with the food product and the surfaces on which contact is indirect.

In the weekly verification of SSOP of the restricted area, Federal Inspectors shall evaluate the records of the establishment, also taking into consideration the sentinel program for *Listeria* sp., focused on the following aspects.

Routine sampling of the environment for *Listeria* sp.

Use the frequency of 5 samples per production line per week, distributed as follows:

- 3 samples of product contact surfaces; and
- 2 samples of surfaces which do not come into direct contact with products, such as: wall switches, drains, aprons, handles, door knobs, among others.

Tests on surfaces of direct contact with products

→ If negative for *Listeria* spp., continue routine environmental sampling.

→ If positive for *Listeria* spp., intensify sampling:

• Collection of 3 samples from the same locations where the surface samples were collected daily, for 3 consecutive days, for *Listeria* spp. (9 consecutive samples from each site, totaling 27 samples).

• If the 9 consecutive samples are negative for *Listeria* spp. – return to routine environmental sampling.

• If one sample is positive, perform sanitization in place as if it were a CCP.

Tests on surfaces that do not come into contact with products

→ If negative for *Listeria* spp., continue routine environmental sampling.

→ If positive for *Listeria* spp., intensify sampling.

• Collection of 3 samples from the same locations where the surface samples were collected daily, for 3 consecutive days, for *Listeria* spp. (9 consecutive samples from each site, totaling 18 samples).

• If the 9 consecutive samples are negative for *Listeria* sp. – return to routine environmental sampling.

• If one sample is positive, continue sampling of 3 samples/location/day until 9 consecutive samples are negative.

Tests on CCP

Collect 3 samples/location/day for 3 consecutive days for *Listeria* spp and *L. monocytogenes* (9 consecutive samples)

→ If the 9 consecutive samples are negative for *Listeria* spp and *L. monocytogenes*, return to routine environmental sampling and eliminate the CCP.

→ If a sample is positive for *Listeria* spp., but negative for *L. monocytogenes*:

• Segregate the product; and

• Release production if the location and production obtain negative results for *Listeria* sp.

Whenever there is a positive case for Listerias on a product contact surface, sanitization of this particular area shall be included in the HACCP plan and monitored as a CCP. The CCP is removed when the establishment proves that the risk to product safety has been eliminated.

Best regards,

CESAR VANDESTEEN JR

FEDERAL AGRICULTURAL INSPECTOR

Chief of DICS/CGI/DIPOA

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
Secretariat of Animal and Plant Health
Department of Inspection of Animal Products
General Coordination Office for Special Programs

Circular nº. 836/2013/CGPE/DIPOA **Brasília, 09/12/2013.**

From: General Coordinator of Special Programs - CGPE/DIPOA

To: Chiefs of the SIPOAs, SISAs, SIFISAs.

Subject: UNITED STATES. SWINE. SUSPENSION. SIF 490.

This Coordination communicates, for appropriate action, which from the day December 9th 2013 the production and certification of establishment under SIF 490 is suspended - SEARA ALIMENTOS LTDA for trade to the United States, considering everything contained in the Process nº. 21000.002982/2013-77.

The authorization for the resumption of production and health certification is conditional upon compliance with the requirements of the United States.

Best regards,

Leandro Diamantino Feijó
Federal Agricultural Inspector
Veterinarian – CRMV/MG 6277
Director of the DIPOA/SDA – Alternate