USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

NOV 0 9 2017

Dr. Odilson Luiz Ribeiro e Silva
Under Secretary of the Office of International Affairs (SRI)
Ministry of Agriculture, Livestock and Food Supply (MAPA)
Esplanada dos Ministérios, Bloco D, Edifício Sede, 3º andar, Sala 300
70.043-900 Brasília, DF BRAZIL

Dear Dr. Ribeiro e Silva,

Enclosed is a copy of the final audit report for the FSIS onsite audit conducted from May 15 through June 2, 2017. The comments received from the Government of Brazil are included as an attachment to the report.

FSIS continues to evaluate your response to the FSIS audit as part of its overall assessment of Brazil's meat inspection system to assure that it remains equivalent to that of the United States. In addition to Brazil's actions in response to the FSIS audit findings, FSIS posed questions regarding Brazil's raw beef and thermally processed, commercially sterile inspection system. FSIS posed these questions, in part, because of trends in point of entry violations indicating potential systematic issues and the subsequent suspension of raw beef exports. The answers to these questions and FSIS's audit findings will guide the scope and frequency of future equivalence verification activities. Future verification activities may include additional in-country audits and increased frequencies at which FSIS reinspects products from Brazil at the United States point-of-entry.

If you have any questions, please feel free to contact me directly at mary.stanley@fsis.usda.gov.

Sincerely,

for Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN BRAZIL

MAY 15 TO JUNE 2, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 6, 2017

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 May 15 to June 2, 2017. The purpose of the audit was to determine whether Brazil's meat inspection system remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. At the time of this audit, Brazil was approved to export raw intact, ready-to-eat (RTE), not ready-to-eat (NRTE) processed, and thermally processed, commercially sterile (TPCS) meat.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs. The FSIS auditors identified the following systemic findings:

Government Oversight

- The Central Competent Authority (CCA) has not developed policies and procedures to identify potential areas where conflicts of interest could arise between inspection personnel and the regulated establishments where they work;
- The CCA does not verify that regulatory information provided to supervisory official veterinarians is consistently communicated to their subordinates;
- The CCA does not verify that in-plant inspectors perform their assigned duties in a manner that is consistent with the issued instructions; and
- The CCA has not developed procedures to standardize the assessment of competence and performance of in-plant inspection personnel assigned to United States-certified establishments.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The implemented post-mortem inspection procedures are inadequate to ensure that only wholesome carcasses, free of contamination and defects receive the mark of inspection;
- Brazilian TPCS product reinspected at United States point-of-entry demonstrates a trend of abnormal container violations; and
- Higher-level officials did not adequately review and follow-up on periodic supervisory reports and plans of action.

Government Sanitation

- Inspection personnel do not adequately enforce sanitation regulatory requirements to prevent the creation of insanitary conditions and direct product contamination.

Government HACCP System

- Inspection personnel do not accurately assess the design and implementation of the establishments HACCP systems, and do not conduct adequate verification sampling of products.

Government Chemical Residue Testing

- The official methods of chemical analysis used by the government laboratories is inconsistent with FSIS requirements; and
- The CCA has not instructed establishments and in-plant inspectors to hold livestock carcasses selected for residue sampling until acceptable results are received.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns identified in the draft final audit report. FSIS will evaluate the adequacy of the proposed corrective actions and base its activities for future equivalence verification on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Brazil's food safety system from May 15 to June 2, 2017. The audit began on May 15, 2017 with an entrance meeting held in Brasilia, Brazil, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Department of Inspection for Products of Animal Origin (DIPOA).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing the meat inspection system maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. At the time of this audit, Brazil was eligible to export raw and processed beef and pork to the United States.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Brazil as a negligible risk country for Bovine Spongiform Encephalopathy. Currently, APHIS maintains restrictions that are in place for imports into the United States of fresh beef and pork due to African swine fever, foot and mouth disease, Rinderpest, classical swine fever and swine vesicular disease. Imports of fresh beef are only allowed from 14 Brazilian states in accordance with special conditions outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §94.29, *Restrictions on importation of fresh (chilled or frozen) beef and ovine meat from specified regions* and imports of fresh pork are only allowed from one Brazilian state in accordance with 9 CFR §94.13, *Restrictions on importation of pork or pork products from specified regions*.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three year period in addition to information obtained directly from the CCA through a self-reporting process.

Representatives from the CCA and local inspection officials accompanied the FSIS auditors throughout the audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, three state inspection offices, and nine local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended. A sample of nine establishments was selected from 25 establishments certified eligible to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent noncompliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These are outlined in 9 CFR §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat.

Additionally, FSIS audited three government laboratories that conduct chemical and microbiological analyses to verify the adequacy of the technical support they provide to the inspection system and to assess the oversight that the CCA maintains over their functions.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central Offices	1	Department of Inspection for Products of Animal Origin (DIPOA)/ Brasilia
	State Inspection Offices	3	Inspection Service of Products of Animal Origin (SIPOA) • State of Goias, Goiania • State of Rio Grande do Sul, Porto Alegre • State of Santa Catarina, Florianapolis
Laboratories		3	• LANAGRO/GO, Goiania • LANAGRO/RS, Porto Alegre • LANAGRO/SP, Campinas
Cattle slaughter and fabrication establishments		3	• SIF 4238, Bataguassu • SIF 4400, Campo Grande • SIF 431, Palmeira de Goias
Swine slaughter, fabrication and processing establishment		1	• SIF 3548, Chapeco
Meat processing establishments (thermally processed-commercially sterile products)		3	• SIF 337, Lins • SIF 226, Hulha Negra • SIF 1690, San Antonio de Posse
Cattle slaughter, fabrication and processing (thermally processed-commercially sterile products) establishments		2	• SIF 2543, Promissao • SIF 385, Andradina

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

- The Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

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

III. BACKGROUND

At the time of this audit, Brazil was approved to export raw intact, ready-to-eat (RTE), not ready-to-eat (NRTE) processed, and thermally processed, commercially sterile (TPCS) and RTE cooked meat products to the United States. From January 2015 to April 30, 2017, FSIS reinspected 170,258,792 pounds of beef and 12,466,998 pounds of pork products exported by Brazil. Of these, FSIS rejected 1,402,384 pounds of beef and 7,904 pounds of pork at POE due to violations of United States food safety requirements including pathology lesions in raw beef, contaminated raw beef, off-condition product, adulteration, and abnormal containers of TPCS meat products.

FSIS has received a Self-Reporting Tool (SRT) from the CCA; however there are still some sections of the SRT that require additional information to adequately describe the Brazilian meat inspection system. The previous FSIS audit report, documenting the audit conducted in November 2015 shows that the components of Brazil's meat inspection system remained equivalent. At that time, however, FSIS identified operational inadequacies regarding the CCA's implementation of its procedures to respond to FSIS POE violation notifications, to target animals suspected of containing violative levels of chemical residues, and to verify that establishments ensure the safety of retort cooling water and retort maintenance.

In addition, FSIS noted deficiencies during the 2015 audit in the enforcement of sanitation standards at several of the audited establishments, inadequate presentation of viscera and carcasses railed out for final veterinary dispositions and inadequate design of inspection stations. At the time of the November 2015 audit, the CCA had not yet initiated exports of raw beef products and had not instituted a *Shiga-toxin producing Escherichia coli* (STEC) proficiency-testing program at its government laboratories. Additionally, the official laboratories lacked procedures for handling inconclusive STEC sample results. FSIS accepted the CCA's proffered corrective actions to address the reported audit findings. The FSIS auditors verified that proffered corrective actions had been implemented during the current audit.

The FSIS final audit reports for Brazil's food safety system are available on 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

On March 18, 2017, the FSIS informed the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) of its decision to implement increased inspection of all meat products exported from Brazil to ensure equivalence in the wake of the Brazilian investigation into bribery scandal involving Brazil's meat inspectors. FSIS instituted 100% reinspection of all Brazilian meat products imported into the United States. This increased level of reinspection has included conducting product examination on 100% of the lots, condition of container examination of

100% of TPCS products, and 100% testing of RTE products for *Salmonella* and *Listeria monocytogenes* as well as testing 100% of beef trimmings from Brazil for *Salmonella* and STEC.

During the post-audit timeframe, FSIS notified MAPA, on June 14, 2017, of an increased number of instances in which raw beef products from Brazil were being found in violation of United States food safety standards at POE. Furthermore, FSIS expressed concerns with regard to MAPA's oversight of the meat inspection system.

On June 22, 2017, FSIS further notified MAPA of numerous, additional POE violations involving presence of abscesses, ingesta, and unidentified foreign material being found in boneless beef trimmings from several United States-certified establishments, which indicated a system-wide problem. That notification also stated that FSIS had refused entry to 45 lots of boneless beef trimmings because they were adulterated by abscesses, ingesta, and unidentified foreign material, thus in violation of the United States FMIA that prohibits the importation of adulterated meat products. FSIS informed MAPA that because of this trend, the decision had been made to suspend the eligibility of imports of all raw beef products from Brazil. In the same notification, FSIS informed MAPA that to resume shipping raw beef products, Brazil needed to carry out a comprehensive review of its food safety inspection program to determine the systemic issues that need to be addressed by the CCA to ensure that all establishments exporting raw intact beef to the United States meet FSIS equivalence requirements.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The FSIS auditors verified that DIPOA, an agency of the MAPA, continues to serve as the Central Competent Authority (CCA) for the meat inspection system of Brazil. DIPOA has several divisions including General Coordination for Inspection, General Coordination for Special Programs, Coordination of Supervision and Inspection, and the International Export and Import Programs Coordination Division, which are involved with production of meat product destined for export to the United States. These divisions of the CCA coordinate to register, audit, certify, and supervise establishments that produce meat products destined for export to the United States.

DIPOA serves as a centralized source of regulatory directives, coordination of personnel development, and program evaluation. The CCA ensures uniform implementation of regulatory requirements and is responsible for oversight of the official activities of inspection personnel at all establishments it certifies as eligible to export meat products to the United States.

At the second level of authority, the State Inspection Service of Products of Animal Origin (SIPOA) represents DIPOA in each one of the Brazilian states. SIPOA offices operate within the scope of federal inspection operations to coordinate at the state level the uniform implementation, supervision, and evaluation of the inspection program at slaughter, meat fabrication, thermal processing establishments, and cold storage facilities certified for export to the United States. The CCA and SIPOA officials grant registration and listing as Federal Inspection Service (SIF) to establishments, after evaluating their facilities to verify that they meet Brazilian government regulatory requirements for the design and construction of their facilities and that their food safety programs meet regulatory standards applicable to interstate or international commerce.

Beginning in 2015, the DIPOA Department of Inspection of Products of Animal Origin (SDA) started to conduct audits to assess food safety controls of United States-certified establishments to determine if they can become or remain listed as eligible for export to the United States. In 2017, DIPOA has changed the scope of the audits to focus on the inspection system, including assessment of two SIPOA offices per year.

The FSIS auditors verified that the CCA has mechanisms in place to ensure that source product used in processing operations originates only from establishments, which are eligible for export to the United States. However, the CCA's instructions on verification of origin of source meat products, prior to the issuing of export certificates, did not include verification of eligibility of imported meat products. This matter was promptly addressed by the CCA. The FSIS auditors verified that the export certification instructions were adequately revised to require that inspection personnel verify that source material originate from eligible countries/establishments. This is accomplished by reviewing the eligibility of foreign establishments with the list of eligible establishments made available by FSIS on its website.[1]

At United States-certified establishments, daily inspection and verification activities are performed by official personnel under the leadership of a Supervisory Official Veterinarian (SOV) who is assisted by additional veterinary and non-veterinary officials to ensure that production activities are conducted in accordance with inspection laws and regulations[2] applicable to the production of meat products eligible for export to the United States. Results of daily inspection activities are recorded in monitoring reports and used to determine the level of compliance maintained by the establishments and to institute enforcement measures that, depending on the degree of significance, could result in suspension of certification or removal from the list of certified SIF establishments. The FSIS auditors verified that the CCA has developed processes to evaluate establishments' written food safety programs, to audit their facilities, and to evaluate their compliance with FSIS requirements before granting them certification of eligibility to export meat products to the United States. However, the design and implementation of the CCA' food safety regulatory controls are inadequate.

[1] Memorando nº 75/2017/CGCOA/DIPOA/MAPA/SDA/MAPA

[2] Law 1.283 Dec. 18, 1950; Law 7.889 Nov. 23, 1989; Decree No. 9.013 Mar. 29, 2017and MP 772/2017 Mar. 29, 2017. *Regulations for the Inspection of Industrial Sanitation for Products of Animal Origin* (RIISPOA), Norma Interna DIPOA/SDA No. 02/2015, DIPOA/SDA 01/2017, and DIPOA/SDA 02/2017.

The CCA follows governmental procedures to maintain its staff levels. Inspection personnel are hired upon demonstrating their suitability for the announced position. However, the FSIS auditors found the following:

- The CCA does not include as part of the in-plant inspection personnel selection, policies and procedures to determine whether the inspectors are free of any potential conflicts of interest that could arise as they begin official duties at the stations where they are assigned to work.

In-plant inspection personnel are government employees that are paid by the Brazilian government regardless of whether they are employed by the federal, state or municipal level of government. The majority of non-veterinary in-plant inspectors are members of the municipal government, while SIPOA officials, most in-plant veterinarians, and technical personnel at the laboratories are federal employees.

Inspection personnel receive induction training during the early stages of their career. From that point forward, in-plant inspection personnel receive training while stationed at United States-certified eligible establishments. Training programs for veterinarians include fundamentals of hazard analysis and critical control points (HACCP), sanitation standard operating procedures (SSOP), microbiological sampling, specified risk materials removal, and ante-mortem and post-mortem inspection of livestock. Ongoing training programs are structured to disseminate instructions and inspection methodology by training SOVs who in turn are expected to train the workforce under their supervision. However, the FSIS auditors found the following:

- The CCA has not developed policies and procedures to verify that SOVs at all certified establishments consistently communicate the ongoing training provided to them to their subordinates.

The CCA communicates import requirements for the United States through a web-based document management system that is available to all inspection personnel via internet services. During the audit, the FSIS auditors verified that transmission of regulatory instructions from the CCA's central offices is accomplished in a prompt and effective manner. Revised instructions for the certification of products for the United States were drafted, approved and disseminated to inspection personnel. However, the FSIS auditors found the following:

- The CCA has not communicated to establishments and in-plant inspectors the FSIS requirements for the holding or maintaining under control livestock carcasses selected for residue sampling until the official test results are reported as acceptable.

The FSIS auditors verified that certified SIF establishments are regularly evaluated by SIPOA officials (i.e., every three months) to assess the adequacy of their food safety systems and to verify compliance with United States requirements. Records and supervisory reports reviewed by the FSIS auditors demonstrate that the CCA provides uniform instructions to in-plant inspection personnel; verifies that in-plant inspection personnel monitor the adequacy of food safety systems; and enforces regulatory requirements that apply to the production of meat products for export to the United States.

The supervisory reports reviewed by the FSIS auditors, document the results of assessments conducted by SIPOA officials at United States-eligible establishments. The reports included identified deficiencies related to the performance of the establishments and in some instances, the overall performance of SIF officials. The CCA stated that the establishments' assessments, which include evaluations of in-plant inspection personnel, are conducted annually.

The FSIS auditors assessed the implementation of official in-plant inspection and verification procedures and noted that although the CCA has issued instructions for the performance of inspection procedures, the inspectors do not always perform their assigned duties in a manner that is consistent with issued instructions and the supervisory review reports had not captured such performance deficiencies. The FSIS auditors found the following:

- When documenting pre-shipment review prior to export certification, in-plant inspection personnel record informal product names of their preference rather than the product name shown on the label, as required;
- In-plant inspection personnel sample lots of beef for microbiological analysis, but do not follow a standardized method that would ensure true randomization of sample selection;
- Inspectors at one beef slaughter establishment did not follow proper procedures for incision and observation during inspection of cattle heads and livers; and
- Official RTE product samples were sent to the wrong laboratory and the method of analysis used was not the method authorized by the CCA for products eligible for export to the United States. Additionally, for one sample, analysis for *Lm* was not performed although the laboratory project code specified *Lm* analysis.

Supervisory personnel at the establishments indicated that the individual performance of in-plant inspection personnel is continuously monitored and remedial actions are instituted when performance shortcomings are identified. However, the approach used to evaluate subordinates in most Brazilian states has not been standardized and the results of those informal evaluations are not documented. Consequently, the CCA could not demonstrate how the competence of individuals assigned to conduct in-plant inspection and verification duties is assessed. The FSIS auditors found:

- The CCA does not have a standardized method for supervisors to evaluate and document the competence levels and performance of individual in-plant inspection personnel.

The CCA utilizes the services of the laboratories of MAPA to maintain verification sampling and analysis of products as part of its microbiology and chemical residue testing components. The MAPA laboratory network includes four official laboratories (i.e., LANAGROs) located in Sao Paolo, Minas Gerais, Pernanbuco, and Porto Alegre that conduct analyses to meet United States requirements. Currently, only the LANAGRO in Minas Gerais conducts analyses of RTE products for *Lm* and *Salmonella.* All laboratories are overseen by the General Coordination of Laboratory Support (CGAL) of MAPA.

CGAL manages the network of laboratories and is responsible for coordinating, directing, and auditing the public and private laboratories to ensure that they adequately perform their functions to support the inspection system. All the laboratories are audited by CGAL to ensure that they remain accredited in accordance with the ISO/IEC 17025 standard. The LANAGROs are also required to maintain their accreditation, and they are audited by the National Institute of

Metrology, Quality and Technology (INMETRO), which is an agency of the Ministry of Development, Industry and Foreign Trade, that audits the government laboratories to verify their conformance with the ISO 17025 standard.

The FSIS auditors verified that in accordance with the requirements of the ISO/IEC 17025 standard, LANAGROs have available for their entire staff current versions of their quality manual, technical procedures, and other work instructions needed in the laboratories. Personnel assigned to conduct analyses of samples have earned higher education credentials in scientific fields including biology and chemistry.

The laboratory analysts have completed regularly administered proficiency evaluations. The CCA has coordinated with CGAL regarding the implementation of proficiency testing targeted to analysts assigned to conduct STEC analysis. Personnel stationed at the three LANAGROs that conduct STEC analysis have successfully completed their proficiency evaluations. In the Porto Alegre LANAGRO, performing chemical residue analyses, normally the lead analyst is the one who participates in proficiency testing whereas additional analysts have their proficiency checked using spiked or "check" samples and the analysis of reference samples when available.

The results of analyses are provided to SIF and archived by the LANAGROs. Audit reports reviewed by the FSIS auditors demonstrate that the CCA and INMETRO had conducted audits of the laboratories. The laboratories also maintain documentation of responses to the identified non-conformances, specifying the corrective actions, and the results of their implementation.

In conclusion, the audit determined that Brazil's government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at certified establishments. The ongoing analysis of available data and on-site audit verification activities indicate that the CCA has developed administrative processes but their implementation is not adequate to meet the equivalence requirements for this component. The CCA has failed to address weaknesses in its oversight including addressing potential conflicts of interests, training, and performance assessment of individual inspection officials.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection (AMI) of animals; post-mortem inspection (PMI) of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for TPCS products.

The CCA has statutory authority to require that certified establishments comply with regulatory requirements to gain and maintain authorization to export raw and processed meat products to the United States. The CCA's regulatory controls are managed and coordinated at the state level by SIPOA, and SIF ensures delivery of inspection and verification activities at certified establishments with the assistance of municipal government authorities. Inspection officials enforce the regulations of the system to ensure that exported meat products meet Brazilian standards and meet food safety and other consumer protection requirements of the United States.

The FSIS auditors verified that the CCA has notified establishments and inspection personnel stationed at slaughter facilities of FSIS regulatory changes related to control and verification protocols for STEC. The CCA provided instructions to establishments to adopt the SIF definition of a production lot subject to STEC sampling for the purposes of establishing microbiological independence of sampled lots. Establishments are also required to specify the actions that they will take when confirmed positive results are reported by FSIS at POE, and the CCA has defined the regulatory actions that it will implement in those situations. Trace-back mechanisms are already in place to maintain identity of products and their link to cattle suppliers.

The FSIS auditors verified that government inspectors perform AMI on all livestock prior to slaughter. Livestock arrive at the establishments accompanied by documents that attest to their point of origin, ownership, and compliance with drug withdrawal protocols, as well as other identifiers that correspond with the traceability procedures managed by MAPA. Animals are observed at rest and in motion and those that show clinical signs of disease are segregated and placed in a suspect pen to be closely evaluated by a government veterinarian. Government inspectors evaluate the adequacy of AMI facilities and assess compliance of establishments with humane handling requirements imposed by the CCA and importing countries.

The FSIS auditors visited slaughter establishments certified as United States-eligible to export raw beef and pork products to the United States. The FSIS auditors verified that SIF performs PMI at those establishments. Slaughter inspection is provided following staffing protocols that specify line speed and number of official government inspectors required for inspection activities. The establishments present heads, viscera, and carcasses that are properly identified for inspection. FSIS confirmed that in-plant inspectors conduct PMI work under the direct supervision of a slaughter veterinarian (SV), who has legal authority to monitor the adequacy of sanitary dressing and production flow in the slaughter floor.

In-plant inspection personnel conduct PMI procedures of bovine heads, viscera, and carcasses in accordance with inspection procedures described in the instruction manual *Norma de Bovinos 1971*. SIF inspectors are instructed to look for superficial and localized contamination and pathological lesions that include abscesses and masses in both halves of the carcass, and trim and pass the carcass. More severely affected carcasses are to be railed out to a designated station for veterinary inspection and disposition, trimming, and to be identified as "not exportable." However, the FSIS auditors found the following:

- The current location of the SIF carcass inspection station (i.e., right after the carcass splitting step) does not permit the establishment to complete all dressing procedures before the carcasses reach the SIF carcass inspection station;

- The SIF PMI procedures do not include a carcass inspection station where SIF inspectors verify that each carcass is wholesome and free of defects and contamination prior to the final carcass wash;
- Carcass inspection tasks including making incisions into the muscle to expose and incise lymph nodes, trimming, and inspecting for pathology might be preventing the inspectors from adequately assessing the eligibility of beef carcasses to receive the mark of inspection;
- Carcasses that had been inspected and passed by SIF carcass inspectors were still in need of further trimming to remove spinal cords, hair, bruises, dressing defects and stick wounds. This approach to PMI does not meet FSIS requirements. FSIS requires that each carcass receive inspection to ensure that only wholesome carcasses free of contamination and defects receive the mark of inspection.

FSIS has reported to the CCA multiple POE violations that involve the presence of pathological lesions (i.e., abscesses) in raw beef products exported to the United States from certified establishments. The observed audit findings under this component and the reported POE violations illustrate that PMI of Brazilian beef is not adequate to ensure that only wholesome, unadulterated carcasses, free of contamination and defects receive the mark of inspection to meet United States requirements.

The FSIS auditors verified that the CCA requires establishments to ensure that their premises are built in a manner consistent with regulatory specifications to obtain authorization to engage in the production of meat products for human consumption. Government officials from different parts of the CCA regularly evaluate the conditions of the different areas of the establishments, document their findings, and require that establishments implement adequate corrective actions when sanitary deficiencies are identified. Documents generated by the CCA, SIPOA, and SIF that were reviewed by FSIS during this audit, demonstrate that the inspection system requires establishments and government officials to interact to ensure that identified noncompliances are adequately addressed to meet the regulations of the program and the requirements of the United States. However, as noted under the Sanitation component, the system is not consistently effective in ensuring identification and resolution of sanitary deficiencies.

The CCA has attempted to effectively address past POE violations related to abnormal containers of TPCS products reported by FSIS. The CCA required that establishments conducted investigations to find the root cause of the problems and those adequate corrective actions were instituted to address the POE violations. Establishments that shipped abnormal containers have increased the frequency of assessment of the quality of containers to ensure that they meet quality standards and have developed programs that ensure that only products for which incubation periods have concluded are released for export to the United States. However, FSIS auditors found the following:

- The implemented corrective actions do not appear to be fully effective because FSIS continues to identify abnormal containers in lots of TPCS product exported from United States-certified establishments at POE.

SIPOA veterinary officials conduct regular onsite reviews of the performance of the food safety systems of the establishments and the performance of the in-plant inspection program and present their reports to SIPOA management for evaluation. Supervisory reviews are conducted every three months covering specific areas of the establishment food safety programs and their compliance with export requirements for the United States. FSIS reviewed records and reports generated by SIPOA auditors that document assessments of the establishments and in some instances, the assessment of the inspection program. The records demonstrate that deficiencies are identified, documented, and communicated to the establishment. The establishment proposes a plan of action that describes corrective actions and their expected completion dates. In-plant inspection personnel verify that the implementation of corrective actions meets regulatory requirements and adequately addresses the reported deficiencies. However, the FSIS auditors found the following:

- The SIPOA manager's review of an establishment's supervisory review report and plan of action did not address that in-plant inspection personnel had not responded to reported in-plant inspection concerns and the establishment had also omitted its response to a reported noncompliance.

The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. The inspection officials' enforcement of regulatory requirements is inadequate to meet the criteria governing the United States' system of meat inspection.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written SSOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors verified that the CCA requires establishments to monitor the adequacy of the construction of their facilities and develop maintenance programs for equipment and structures to prevent the creation of insanitary conditions. In addition, the FSIS auditors verified that certified establishments develop and implement written SSOPs that are designed to prevent direct product contamination. The CCA has developed regulatory instructions for government officials to verify the compliance of certified establishments with sanitation requirements on a daily basis.

The FSIS auditors reviewed establishment and government inspection records that document the results of the establishments' monitoring of the implementation of their sanitation programs and the results of inspection and verification activities conducted by in-plant inspection personnel prior to the beginning of operations and during the duration of the production processes. The records demonstrate that the sanitation program is implemented daily. Sanitary deficiencies are documented and eliminated by the establishment when identified by either the establishment, or inspection officials.

The FSIS auditors verified the adequacy of official verification and inspection activities of the establishments' sanitation programs maintained by SIF by observing government inspectors as they assessed the implementation of the establishments' sanitation procedures for pre-operational and operational sanitation. The FSIS auditors also assessed the overall sanitary conditions of production areas, product handling practices, and storage rooms, and observed the production processes conducted at slaughter, fabrication, processing, and thermal processing establishments.

The FSIS auditors noted that the inspection and establishment records were generally representative of the actual sanitary conditions of the establishment. However, the FSIS auditors found deficiencies in multiple establishments as follows:

- Sanitation Performance Standards: In five of the nine audited establishments, poor maintenance of the facilities had created surfaces difficult to clean and sanitize;
- Sanitary Operations:
  - In two of the four raw meat product exporting audited establishments, direct product contamination was occurring, specifically:
    - At one establishment, beef carcass hindquarters were contaminated with rail dust, a strip of hair on hide, and a thick smear of a green/brown substance were entering the deboning room; and
    - At one establishment, SIF permitted reconditioning of raw pork that accidentally fell to the floor in the deboning department, but the establishment did not have written standard operational procedures that it would follow to ensure that reconditioning of product was done in a sanitary manner at a properly equipped station.
- Corrective Actions Deemed Inadequate: Carcasses moving on the chain rail were dragging across the flooring face plate of an inspection stand. The deficiency had been first identified by the CCA in 2014, but had not been completely corrected.

The aforementioned audit findings were communicated to SIF in-plant personnel at the establishments audited, who in turn provided official notification to the affected establishments, requesting corrective actions.

The FSIS auditors verified that the meat inspection system of Brazil has developed regulatory requirements for all certified establishments to implement sanitation programs, however as described above, the design and implementation of those programs is inadequate to prevent the creation of insanitary conditions and prevent direct product contamination.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditors verified that the CCA requires that certified establishments implement SSOPs and prerequisite programs as part of their HACCP systems to be authorized to export their products to the United States. SIPOA and SIF officials have the legal authority to verify that

establishments' conduct a hazard analysis for each step in their production processes, and implement HACCP plans to control hazards deemed as reasonably likely to occur. The CCA has issued instructions to establishments and inspection personnel that specify hazards that are to be controlled in the production of meat products. Establishments must implement controls to ensure that carcasses are free of fecal matter, ingesta, and milk contamination. Raw beef products are to be free of STEC and RTE meat products must be free of *Lm*, *Escherichia coli* O157:H7, and *Salmonella.*

SIF officials at the establishments certified to export to the United States verify implementation of the establishment's HACCP plans, critical control points (CCPs), and the adequacy of corrective actions, and verify recordkeeping; detect noncompliances and collect product samples for official verification of the adequacy of food safety controls. Verification of compliance of establishments with United States for zero tolerance requirement for feces, ingesta and milk on carcasses, is conducted daily, by examining ten randomly selected carcasses.

The FSIS auditors reviewed documents and records to assess the establishments' HACCP monitoring and verification activities, and SIF implementation of regulatory enforcement. The review of documents showed that the establishments prepared written hazard analysis, flow charts, and HACCP plans. Establishments that export TPCS products to the United States are required by the CCA to implement process controls to ensure an adequate thermal process. Establishments producing TPCS products are also required to maintain prerequisite programs designed to ensure that the containers meet requirements for hermetically sealed containers. The FSIS auditors observed that during days of production, containers (e.g., cans, pouches) are subject to evaluations to verify that the seam closure tests are conducted to ensure their suitability and the results are entered into an automated system that tracks the performance of equipment and containers. HACCP plans describe the hazards to be controlled, the critical limits, monitoring frequency, corrective actions, and verification procedures.

During the audit of TPCS establishments, the FSIS auditors reviewed records documenting the actions taken by the establishment to respond to CCP deviations related to inadequate closure of containers. The corrective actions implemented by the establishment were consistent with the HACCP plan prepared for that CCP, and SIF personnel had been informed of the event and corrective actions that were taken.

In addition, establishments had documented actions taken to address POE violations reported by FSIS related to presence of mold on dry beef products. The establishments have conducted an evaluation of the packaging materials and methodology of packaging of the product to prevent damage of containers and to ensure that hermetic closure was adequately maintained.

The FSIS auditors determined that SIF officials verify implementation of HACCP systems. However, the FSIS auditors found the following:

- One audited establishment lacked documentation to support decisions in the hazard analysis. There was no reference to the procedures the establishment implements to ensure the safety of the water it uses in the production processes, though effective controls are in place to meet sanitary requirements for water in the different steps of the processes;

- Product sampling conducted by an establishment to verify adequacy of STEC controls is to be conducted following N60 methodology, thus requiring random collection of sixty pieces of meat from a lot of beef product. However, rather than collecting the required 60 pieces of beef, the establishment technicians were focusing on collecting 800 grams of meat from the sampled lot; and
- Official verification of establishments' microbiological controls for STEC requires that SIF inspectors collect beef product samples in accordance with prescribed methodology that calls for sampling at least five packages of product to obtain 60 pieces of beef. However, inspection personnel did not follow the instructions and selected one box from a given lot of beef products and from that box collected 60 pieces of meat that formed the sample to go to the laboratory for microbiological analysis.

In conclusion, the FSIS auditors verified that the CCA requires regulated establishments to develop and implement HACCP programs. However, the oversight provided by the CCA is ineffective.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to include present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

The FSIS auditors verified that the General Coordination of Inspection division oversees the Coordination of Supervision and Inspection, which manages the National Program for the Control of Chemical Residues and Contaminants (PNCRC). The PNCRC was established by Ministerial Decree Nº 51 on May 6, 1986, and by Ministerial Decree Nº 527, on August 15, 1995, to maintain regulatory control and surveillance of products to prevent violation of safety standards or maximum residue levels (MRLs) for allowed substances and the occurrence of residues and chemicals banned for use in the country at all levels. For this purpose, SIF in-plant personnel collect tissue samples from slaughtered livestock at certified establishments in accordance with the national sampling plan, the samples are analyzed at accredited laboratories using approved analytical methodology, and the results are provided to the CCA headquarters office for assessment and distribution. However, the FSIS auditors found the following:

- The CCA has not communicated to establishments and in-plant inspectors the FSIS requirements for the holding or maintaining under control, livestock carcasses selected for residue sampling, until the official test results are reported as acceptable

The FSIS auditors visited chemical residue testing laboratories, state and local government offices, and slaughter establishments to verify the adequacy of implementation of the PNCRC. At the establishments, the FSIS auditors observed that SIF personnel follow a schedule for the collection of samples and send the samples to specified laboratories. The laboratories conduct analyses of tissues (i.e., fat, organs, and muscle) collected at bovine and swine slaughter

establishments. The samples are analyzed using validated screening, confirmation and quantification methods of analysis approved by the CCA and FSIS.

The laboratories have the ability to detect and/or quantify residues of veterinary drugs, anthelmintics, and environmental contaminants and readily communicate the results of the analysis to the stakeholders. The FSIS auditors verified that in accordance with the accreditation requirements the laboratories maintain a program of internal audits to verify the daily implementation of the requirements of the ISO/IEC 17025 standard. However, the FSIS auditors found the following:

- Laboratory personnel were not following proper protocol, required by the ISO/IEC 17025 standard, for the displaying of annual calibration certificates for analytical equipment and the handling of reagents. Several bottles of unidentified reagents had been left on the bench. Reportedly, the substances had been used during equipment calibration one month earlier; and
- If the initial residue analysis detects a residue, a second sample aliquot is extracted from the original tissue sample and three additional separate analyses are performed to verify the initial results. The average of the analyses is used to determine the result. This methodology is not consistent with FSIS requirements.

At the establishment level, trained SIF personnel collect, package and send the samples to the laboratories in accordance with standardized procedures that ensure prompt delivery of properly identified samples. The laboratories receive the samples and generate records throughout the analytical process to report methodology used and results of the analysis. Laboratories are managed and operated by personnel that possess academic credentials in chemistry and other scientific fields that have been supplemented with short-term training completed overseas at specialized centers of learning. The CCA requires that the laboratories meet and maintain accreditation requirements in accordance with the ISO/IEC 17025 standard and that they participate in proficiency testing programs to maintain accreditation and to expand the scope of their analytical capabilities.

In conclusion, the analysis and on-site audit verified that this component includes a national residue program that is managed and implemented as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The inspection system is to implement certain sampling and testing programs to ensure that meat products destined for export to the United States are safe and wholesome.

The FSIS auditors reviewed the CCA Pathogen Reduction Standards related to generic *E. coli* and *Salmonella* Performance Standards, as well as Brazil's STEC control program. In addition, the FSIS auditors performed an onsite assessment of the implementation of the microbiological sampling and testing of raw and cooked meat products conducted by establishments and government officials.

The documents reviewed demonstrate that the CCA administers a national regulatory microbiological monitoring program for establishments producing meat products for export to the United States. The program provides indicators of the adequacy of sanitary dressing procedures and production practices, and verification of the effectiveness of the establishments' food safety controls designed to control microbiological pathogens. Furthermore, the CCA requires that establishments hold all tested products until the results of microbiological testing are received and authorization for export to the United States is issued by in-plant inspection officials.

The FSIS auditors confirmed that laboratories conducting microbiological analysis of samples of eligible meat products from certified establishments are audited by the accrediting organizations and CGAL on behalf of the CCA, in accordance with the requirements specified in ISO/IEC 17025 standard and are required to participate in proficiency testing programs.

Documents reviewed by FSIS and observations made at certified slaughter establishments demonstrate that testing of raw products for generic *E. coli* and *Salmonella* is conducted at slaughter facilities. Shipping and handling of randomly collected samples is done by the establishments under the supervision of in-plant government inspection officials and in accordance with instructions issued by the CCA.

The CCA implements *Salmonella* testing for chilled livestock (cattle and swine) carcasses based on the FSIS *Salmonella* performance standards. Establishments that fail the first *Salmonella* set must take immediate corrective action and reassess their HACCP plan. If the subsequent second set of samples fails to meet the performance standard, then the HACCP plan is audited by SIPOA, and another sampling set is initiated. If an establishment fails three consecutive sample sets, it is removed from the list of United States-eligible establishments. The suspension would remain in effect until the establishment achieves the performance standard. The CCA's *Salmonella* performance standards for bovine ($n = 82$, $c \leq 1$) and swine ($n = 55$, $c \leq 6$) are the same as FSIS' standards. The samples are collected by establishment personnel under the supervision of SI. The samples are analyzed using FSIS methods at CCA-approved private laboratories that are regularly audited by CGAL.

SIF officials verify the adequacy of establishments' generic *E. coli* testing program in chilled livestock carcasses to ensure the programs meet the requirements outlined in the CCA's instructions provided in the *Microbiological Tests on Livestock Carcasses (835/2006)* and *Interpretation of Generic E. coli Results (1058/2008),* that have been determined equivalent by FSIS. The FSIS auditors verified that the establishments and inspection personnel are familiar with the upper and lower control limits, as well as the corrective actions to be taken when the upper limits are exceeded. The records reviewed show that process control is being maintained at the certified slaughter establishments audited.

The CCA maintains a verification testing program to test for *Lm* and *Salmonella* species in RTE products, and requires that certified establishments exporting RTE products to the United States implement a program to meet FSIS equivalence criteria to control *Lm* through their HACCP plans or prevent it in the processing environment. The CCA verifies the adequacy of the

implemented practices by conducting RTE product and food-contact surface sampling on a monthly basis. The collected samples are analyzed by the LANAGRO located in the state of Minas Gerais.

The FSIS auditors assessed the STEC control program managed by the CCA. The CCA tests raw ground beef components destined for export to the United States monthly and requires 'test and hold' for all sampled lots. Additionally, in *Circular 3/*2017, the CCA prescribes the definition of a lot of product for STEC control verification sampling. A lot of product must represent one unit of production with the same characteristics and a maximum weight of 4,760 kilograms.

In conclusion, the FSIS auditors' document analysis and on-site verification activities demonstrate that Brazil's meat inspection system includes requirements for microbiological sampling and testing programs. The microbiological testing program as described is consistent with the criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 2, 2017, in Brasilia, Brazil with DIPOA and CGAL officials. At this meeting, FSIS auditors presented the preliminary findings from the audit
A summary of the identified systemic findings follows:

Government Oversight

- The Central Competent Authority (CCA) has not developed policies and procedures to identify potential areas where conflicts of interest could arise between inspection personnel and the regulated establishments where they work;
- The CCA does not verify that regulatory information provided to supervisory official veterinarians is consistently communicated to their subordinates;
- The CCA does not verify that in-plant inspectors perform their assigned duties in a manner that is consistent with the issued instructions; and
- The CCA has not developed procedures to standardize the assessment of competence and performance of in-plant inspection personnel assigned to United States-certified establishments.

Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations

- The implemented post-mortem inspection procedures are inadequate to ensure that only wholesome carcasses, free of contamination and defects receive the mark of inspection;
- Brazilian TPCS product reinspected at United States point-of-entry demonstrates a trend of abnormal container violations; and
- Higher-level officials did not adequately review and follow-up on periodic supervisory reports and plans of action.

Government Sanitation

- Inspection personnel do not adequately enforce sanitation regulatory requirements to prevent the creation of insanitary conditions and direct product contamination.

Government HACCP System

- Inspection personnel do not accurately assess the design and implementation of the establishments HACCP systems, and do not conduct adequate verification sampling of products.

Government Chemical Residue Testing

- The official methods of chemical analysis used by the government laboratories is inconsistent with FSIS requirements; and
- The CCA has not instructed establishments and in-plant inspectors to hold livestock carcasses selected for residue sampling until acceptable results are received.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns identified in the draft final audit report. FSIS will evaluate the adequacy of the proposed corrective actions and base its activities for future equivalence verification on the information provided.

APPENDICES

Appendix 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. Andradina, Sao Paulo Brazil	May 22, 2017	SIF 385	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	X
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters and processes beef for export to the United States. It mainly produces raw trimmings and canned beef products. It supplies raw materials to SIF 337.

55. Veterinarians monitor their subordinates' performance but they don't follow a standardized approach to evaluate and document adequacy of their performance. During observation of post-mortem inspection activities, the FSIS auditor noted that the procedure followed by the inspector did not include incision of the biliary duct in both directions as FSIS standards require. In addition, Brazil's procedure for post-mortem inspection of heads calls for careful incision and observation of cut surfaces to detect lesions that might indicate the presence of pathogen that colonize lymph nodes. However, one inspector was seen bluntly and hurriedly incising the tissues of the head and proceeding to trim structures from the head, as part of his on line inspection routine.

The government slaughter veterinarian indicated that when subordinate's performance is less than desirable, the official is corrected, but does not make a formal record of the actions taken or the results of the intervention. The veterinarian does not follow a standardized approach to evaluate and document the level of competence and performance of subordinates.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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
Meat Snack Partners do Brazil San Antonio de Posse, Sao Paolo	5/29/17	SIF 1690	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
		41. Ventilation	
14. Developed and implemented a written HACCP plan .		42. Plumbing and Sewage	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	43. Water Supply	
16. Records documenting implementation and monitoring of the HACCP plan.		44. Dressing Rooms/Lavatories	
17. The HACCP plan is signed and dated by the responsible establishment individual.		45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.		47. Employee Hygiene	
19. Verification and validation of HACCP plan.		48. Condemned Product Control	
20. Corrective action written in HACCP plan.		**Part F - Inspection Requirements**	
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.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment processes cooked dry beef for export to the USA.

51. A formal documented evaluation of the performance of individual inspectors is not implemented. Veterinarians do not follow a standardized approach to evaluate the performance of their subordinates. Furthermore, the record of the last review of the report and plan of action prepared for this establishment shows that, missing responses to in-plant inspection concerns, and incomplete responses to a reported non-compliance were omitted from the scope of the review.

The completion of the pre-certification inspection form asks the inspector to describe the product in the space provided in the form, as it appears on the label. The inspector however, describes the product using other product name, thus acting against issued instructions.

15. Soy and wheat are recognized as allergens in the list of ingredients used at this establishment and the company maintains controls for the hazard represented by allergens from receiving through storage. However, the hazard analysis conducted at the ingredients storage step does not list them as hazards reasonably likely to occur.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

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 S.A. Promissao, Sao Paulo Brazil	May 19, 2017	SIF 2543	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	X
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
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28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters and processes beef for export to the United States. It mainly produces cooked frozen and canned and pouched beef products using raw materials received from approved establishments.

39. In close proximity to the point of exit of edible products from a mixer, exposed wires at the end of an electric conduit had accumulated organic residue on their surfaces and in another production area, there was a dislodged conduit cap that had allowed greasy materials and red discolored organic residue to accumulate on its surfaces, creating areas difficult to clean and sanitize.

49. The government slaughter veterinarian does not follow a standardized approach to evaluate and document the level of competence and performance of subordinates.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 S.A. Bataguassu, Sao Paulo Brazil	May 23, 2017	SIF 4238	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	X
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters and processes beef for export to the United States. It mainly produces raw fresh beef products.

49. Veterinarians monitor their subordinates' performance but they don't follow a standardized approach to evaluate and document their level of competence and adequacy of the performance.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 RDV BR 060 Sn Km 359.8 Margen Direita, Zona Rural Campo Grande Matto Grosso do Sul	5/25/17	SIF 4400	Brazil
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	X
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
		41. Ventilation	
14. Developed and implemented a written HACCP plan .		42. Plumbing and Sewage	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		43. Water Supply	
16. Records documenting implementation and monitoring of the HACCP plan.		44. Dressing Rooms/Lavatories	
17. The HACCP plan is signed and dated by the responsible establishment individual.		45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	
18. Monitoring of HACCP plan.		47. Employee Hygiene	
19. Verification and validation of HACCP plan.		48. Condemned Product Control	
20. Corrective action written in HACCP plan.		**Part F - Inspection Requirements**	
21. Reassessed adequacy of the HACCP plan.		49. Government Staffing	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		50. Daily Inspection Coverage	
Part C - Economic / Wholesomeness		51. Enforcement	X
23. Labeling - Product Standards		52. Humane Handling	
24. Labeling - Net Weights		53. Animal Identification	
25. General Labeling		54. Ante Mortem Inspection	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		55. Post Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		**Part G - Other Regulatory Oversight Requirements**	
27. Written Procedures		56. European Community Directives	O
28. Sample Collection/Analysis		57. Monthly Review	
29. Records		58.	
Salmonella Performance Standards - Basic Requirements		59.	
30. Corrective Actions			
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters and processes raw beef for export to the USA.

49. A formal documented evaluation of the performance of individual inspectors is not implemented. Veterinarians do not follow a standardized approach to evaluate the performance and level of competence of their subordinates.

51. Government officials follow instructions issued by the CCA to sample the product every 15 days, by randomly selecting sixty pieces of product from a given lot. However, they do not follow a standardized method to ensure true randomization of sample selection.

The description of the product presented by the company for certification is not consistent with the name of the product as it appears on the label. Inspectors do not use the name of product as appears on the label, as instructed.

33. The establishment's STEC program defines its sampling program for raw beef for export to the USA, as N-60, however, the plan does not emphasize collection of a given number of pieces of product from a given lot but rather a specific weight.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

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
Pampeano Aliminetos S/A Estação Santo Antonio Km 32 Vila Bordon Hulha Negra	05/24/2017	SIF-226	Brazil
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. 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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

19/51 HACCP Verification and Validation

The establishment produces ready-to-eat (RTE) beef jerky and performs RTE product sampling to verify their food safety system controls are effective in ensuring finished products are free of *Salmonella spp.* and *Listeria monocytogenes*. However, the accredited laboratory is analyzing 25 gram samples for *Salmonella*. In order to have confidence in the establishment's results the establishment should be analyzing a sample portion providing equivalent results to FSIS methods (e.g., 325 gram).

39/51 Establishment Construction/Maintenance – Walls, Floors

The raw meat chilling room had deteriorated concrete flooring resulting in two depressed areas retaining water and blood. The concrete coving at the floor/wall interface was also in poor repair with significant cracks and gaps at the junctures resulting in an inability to thoroughly clean these areas.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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, Sao Paulo Brazil	May 18, 2017	SIF 337	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. 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	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

This establishment stopped slaughter activities designed to supply beef for export to the United States. It mainly produces cooked frozen and canned and pouched beef products using raw materials received from approved establishments.

15. The establishment does not mention or makes reference to the procedures it implements to ensure the safety of water used in the processes. However, the establishment has developed a multitier approach to control the microbial quality of the water. The controls include controls at points of collection and sampling in accordance with Brazil regulations, and interventions that render the water acceptable.

45. Organic residue had accumulated on the surfaces of the rollers where trays of cans and pouches are transported. The frequency of cleaning of those surfaces was reportedly occurring on a weekly basis, but an assessment of multiple sites where the problem was present indicates that such frequency might not be adequate to ensure sanitary conditions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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
Minerva Foods S/A Palmeiras de Goiás, GO Brazil	05/18/2017	SIF-431	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	X
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10/51 Implementation of SSOPs

Multiple hindquarters entering the deboning room on a rail were observed by the FSIS auditor to have direct product contamination including rail dust, a 1.5 inch piece of hair on hide strip on one quarter and one quarter with an extensive thick smear of green/brown substance across the entire cut surface of the hock and around the contact points with the carcass hook. The establishment's SSOP plan failed to prevent direct product contamination.

22/51 HACCP Records

HACCP monitoring records for CCP1B did not include actual time and initials and ongoing verification records do not include the date, time, type of ongoing verification activity, or results.

35/51 Residue

The CCA has not issued instructions to establishments and in-plant inspectors that require the establishment to hold or maintain control over any livestock carcass selected for directed monitoring residue sampling under the national residue plan (PNCRC) until the official test results are reported. Consequently, the establishment may export carcasses or parts with violative residues to the United States. This is a repeat finding from the 2015 FSIS audit.

39/51 Establishment Construction

Multiple deficiencies in the maintenance of overhead structures were observed by the FSIS auditor in the slaughter and deboning and repack rooms. Observations included rusty cables over the high legging stand and evisceration stands. In the repack room, there was an approximate 1.5 inch hole in a metal plate around a pipe where it passed through the ceiling. There were multiple gaps around other pipes where they passed through the ceiling. In multiple locations the seams of the overhead ceiling were separating and resulting in gaps and rusty discoloration. These findings created insanitary conditions that could lead to product contamination.

In the deboning room and other product hallways throughout the facility there were multiple areas with deterioration of the concrete floor resulting in wide and deep cracks and divots. There were several areas where the concrete coving at the wall/floor juncture was deteriorating with broken and rough surfaces and cracks. These areas cannot be effectively cleaned and result in the accumulation of moisture and water in low points, thereby creating insanitary conditions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 Brazil	05/30/2017	SIF-3548	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

7, 11 /51 Written SSOPs; Sanitary Operations

The FSIS auditor observed a stainless table with meat particles used to recondition dropped product in the deboning room. The reconditioning table and area lacked a lavatory for hand-washing and lacked a means of sanitizing utensils used to trim product during the reconditioning process. Review of the establishment's written SSOP plan revealed a lack of specific procedures to be followed by establishment personnel when reconditioning product that had fallen to the floor. The establishment's stated practice is to clean the table between breaks by wiping and spraying with 70% alcohol. The procedures as described are inadequate to ensure sanitary practices are developed, implemented, monitored, and maintained. The SIF personnel failed to identify the insanitary practices during reconditioning and the lack of specific written procedures sufficient to ensure a sanitary process and prevent cross-contamination of products and surfaces.

11, 46 /51 Implementation of SSOPs; Sanitary Operations; Equipment

At the carcass splitting station the FSIS auditor observed direct contact of carcasses with non-food-contact and insanitary surfaces including the housing cover of the split saw motor, the discharge hose, and electric supply cord was noted for repeated carcasses. In addition, there was extensive build-up of organic debris and blood on the FCS below the split saw. The SIF personnel failed to identify this deficiency. The establishment implemented short-term corrective actions.

11, 39 /51 Maintenance and Evaluation of SSOPs; Construction

The FSIS auditor identified that the face plate at the foot of the zero tolerance stand is constructed of painted iron and included gaps between the face plate and perpendicular base. The surface is contacted by carcasses moving on the chain rail. The surface is not amenable to thorough cleaning and sanitizing. This deficiency was first identified during a supervisory visit in 2014 and has subsequently been identified during supervisory visits and by SIF as an area requiring modification. Despite the deficiency being documented by SIF personnel on multiple occasions over the previous 2.5 years, the establishment corrective actions and SIF verification process has been inadequate in ensuring resolution of the finding.

22/51 HACCP Records

The establishment HACCP monitoring records did not include the time and initials for each monitoring result.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

Appendix B: Foreign Country Response to Draft Final Audit Report

ANNEX

Response of the competent authorities of Brazil to the recommendations of report of the audit carried out from May 15 to June 2, 2017 to evaluate the food safety systems governing meat products exported to the USA.

N°	*Recommendation*	*Action Proposed by the Central Competent Authority*
01	The Central Competent Authority (CCA) has not developed policies and procedures to identify potential areas where conflicts of interest could arise between inspection personnel and the regulated establishments where they work.	The civil servants who work in the inspection are subject to the legislation on conflicts of interests as per below: I - Decree 1,171 of June 22, 1994 that approves the Code of Professional Ethics of Public Civil Servants of the Federal Executive Branch; and II - Decree 6,029 of February 1st, 2007 that creates the Ethics Management System of the Federal Executive Branch; and lays down other provisions. Any investigations of cases of conflict of interest within the scope of MAPA can be conducted by the Ethics Commission whose competencies are defined in Ordinance (Portaria) 604, dated August 18, 2009, or the Internal Affairs (Corregedoria)/SE/MAPA, as set forth in Article 6 of Decree 8,852, dated September 20, 2016. We shall highlight that the Internal Affairs (Corregedoria)/SE-MAPA has similar tasks to the USDA general inspector, except for the power to send to prison or conduct a crime investigation, which are performed by the Judiciary Power, the Federal Police and the Federal Public Prosecutor's Office in Brazil. The Ministry of Agriculture (MAPA) has the following main channels to receive accusations: 1) Website: http://www.agricultura.gov.br/ouvidoria/ouvidoria; 2) Relationship Center: 0800 704 1995; 3) e-mail: ouvidoria@agricultura.gov.br; and 4) hearing with the Ombudsman: (61) 3218-2089/Address: Esplanada dos Ministérios – Bloco “D” – Ed. Sede - 2º andar - sala 202. Any citizen, businessperson or civil servant can make an accusation using either investigation channel. We also stress that the entire team of civil servants who work at the inspection of an establishment eligible to export to the United States is exclusively paid by the Government, whether Federal, State or Municipal. This is defined in Circular n° 111/2015/CGPE/DIPOA of December 3, 2015.

		This condition is compulsory for an establishment to be added to the list of exporters and is verified in the approval process according to item 12 of Appendix II of Memorandum-Circular 176/2016/DHC/CGI/DIPOA, of July 15, 2016, and periodically verified for the approval to be maintained as per subparagraph II, item 3, of Memorandum 69/2016/CGCOA/DIPOA. Those civil servants granted to MAPA through Technical Cooperation Agreements (TCA) undergo public selection (public competition or simplified public selection procedures) MAPA does not have a hierarchy over the State or Municipal authority that granted the civil servants to work at the Federal Inspection Service (SIF) and does not interfere with the selection processes performed by them. If the granted civil servant does not perform appropriately at the Federal Inspection Service (SIF), MAPA requests the granting authority to replace him/her. It is also important to highlight that the investigation on the "weak flesh" operation by the Federal Police lasted over two years and used legal instruments authorized by the courts such as wire taps, lifting tax and banking secrecy, which are not available to MAPA at the management level (as it has already been informed, this type of investigation can only be authorized/led by the Judiciary Branch, the Federal Police or the Federal Public Prosecutor's Office). Each entity in the Federal Public Administration of Brazil plays a well-defined role to determine any wrongdoings within their area of operation. Examples that the system is able to detect, investigate and punish any civil servants involved in wrongdoings (including conflicts of interest) are: operations by the Federal Police that resulted in civil servants' imprisonment or lay off; the Ombudsman of MAPA received 145 accusations in July 2017 (64 have been completed and 81 are under investigation at the technical departments); and 56 audits have been triggered by DIPOA/SDA in animal product establishments (meat, milk, eggs, honey and fish) to clarify these accusations.
02	The CCA does not verify that regulatory information provided to supervisory official veterinarians is consistently communicated to their subordinates.	All the information issued by DIPOA/SDA that needs to be communicated to the civil servants who work at the Federal Inspection Service (SIF) is published in the Management Information System of the Federal Inspection Service (SIG-SIF). This system is accessed on the Internet with an exclusive civil servant user and password: The team of local inspection civil servants is comprised of official veterinarians (which correspond to PHV) and to inspection agents (which correspond to CSI or food/line inspectors). Most of the information is disclosed to the official veterinarians. However, if the published information needs to be conveyed to the inspection agents, the official veterinarian must make sure that is done. The conveyance of information from the official veterinarian to his/her team may or may not be recorded. When it is recorded, it is done through an official communication - a letter (ofício) or memorandum - or through training.

		It must be highlighted that, in addition to daily guiding and assessing the work of the inspection agents by the local official veterinarian (there is no official form for that assessment, neither an established frequency), the performance of the team is assessed every 3 months in Part II of the Supervision Report form set forth by DIPOA/SDA Internal Standards (Norma Interna) 2/2017. Failure to perform the Official Service procedures due to outdated regulatory information is entered by the Supervisor in Field 11 of Part 2 of the report for slaughterhouses, or in field 8 of Part 2 of the report for non-slaughter plants. Supervisions in the establishments eligible to export to the US are conducted by an external team, that is, by civil servants who do not work in that particular plant neither in another plant eligible to export to the US.
03	The CCA does not verify that in-plant inspectors perform their assigned duties in a manner that is consistent with the issued instructions.	The answer to this finding has been given in Item 2.
04	The CCA has not developed procedures to standardize the assessment of competence and performance of in-plant inspection personnel assigned to United States-certified establishments.	The performance of the inspection staff is performed in three ways: a periodical assessment regulated by MAPA's administrative level, a periodical assessment during a Supervision or Audit, and continuous assessment by the official veterinarian on his/her team of civil servants. The assessment regulated by MAPA's administrative level is described in the following link: http://agronet.agricultura.gov.br/servicos-menu-lateral/avaliacao-de-desempenho. The assessment made by the official veterinarian or during a Supervision or Audit has been detailed in item 2. We highlight that, differently from what a front line supervisor finds in the evaluations performed in teams of FSIS employees, in Brazil the inspection team is assessed by the Supervisor and the findings are recorded as described in item 2. The conclusion of the FSIS auditors is not grounded because it was based on isolated findings such as: an incorrect filling out of the pre-shipment review (the corrective measures have been reported in the action plan for SIF 4400), the lack of randomized official sampling for STEC tests (the corrective measures have been described in item 9), non-compliance in the post mortem procedures in head and liver inspection lines (the corrective measures have been reported in the action plan for SIF 385) and the non-compliance to send beef jerky samples for microbiological testing to an inappropriate official laboratory (the corrective measures have been reported in item 10). All these findings and their corrections have been commented in this action plan and its appendices.

05	The implemented post-mortem inspection procedures are inadequate to ensure that only wholesome carcasses, free of contamination and defects receive the mark of inspection.	During the post mortem inspection, in Brazil, the inspection lines for beef carcasses guarantee that 100% of the carcasses are inspected by the Official Service, whether on the medial or lateral sides, searching for any visible contamination (including fecal, ingesta or milk contamination), and their removal is mandatory either in the inspection line or at the Final Inspection Department (DIF) (a similar facility to the final disposition in the US), when there is a more extensive contaminated area or if the contamination requires more time and attention. The average speed of slaughter in Brazil is much slower than in the US. Slaughter speed is a relevant factor for the inspection lines to be staffed. As a standard, there are two inspection agents on the high platform (who inspect the upper part of the carcasses) and one inspection agent on the low platform (who inspects the lower part of the carcasses). The local official service has the autonomy to allocate one more inspection agent to perform the procedures in the upper or lower carcass inspection lines, if necessary, and considering the minimum time to carry out the inspection. Trimming of contamination by the official service does not impair health inspection. The inspection procedures were strengthened by Memorandum n° 40/2017/DIPOA/SDA of July 23, 2017. It is important to highlight that monitoring and verification of CCP 1B (zero tolerance for ingesta, fecal and milk contamination) performed by the establishments does not replace the carcass official inspection lines under no circumstances. Another important point to be stressed is that the official verification of CCP 1B by the local official service, based on DIPOA Internal Standards (Norma Interna) 01/2017 and Memorandum 52/2017/CGCOA/DIPOA does not replace the carcass official inspection lines under no circumstances.
06	Brazilian TPCS products reinspected in the United States point-of-entry demonstrate a trend of abnormal container violations.	The control procedures applied to the manufacturing of heat-processed products have been reviewed as per Memorandum n° 113/2017/CGCOA/DIPOA of July 16, 2017. It is an additional and temporary measure that shall prevail until the revision of the regulations in Circular n° 028/DICAR, of June 19, 1978, and Circular n° 285/2005/CGPE/DIPOA of June 24, 2005. The effectiveness of the measures is proved by the marked decrease in the number of violations at the POE for this product category.
07	Higher-level officials did not adequately review and follow-up on periodic supervisory reports and plans of action.	This conclusion was based on the following finding: "The SIPOA manager's review of **AN** establishment's supervisory review report and plan of action did not address that in-plant inspection personnel had not responded to reported in-plant inspection concerns and the establishment had also omitted its response to **A** reported noncompliance." (our emphasis) This non-compliance is isolated and does not support the conclusion of the FSIS/USDA auditors. It has been corrected according to the corrective measures in SIF 1690 establishment's action plan. It must be clarified that the goal of DIPOA/SDA (CCA) is to audit two SIPOA/SISA/SIFISA (*District Offices*) per year according to Circular n° 088/2015/CGI/DIPOA, of November 6, 2015. In this Service audit, the report form in the Appendix of Memorandum 02/2016/CGCOA/DIPOA, of May 18, 2016, is used and has a directed verification of a sample of 10% of the Supervision Reports issued and of the analysis of SIPOA/SISA/SIFISA made on these reports (Fields 10 and 11 of the Service audit report).

		Seven Services have been audited since 2015 and non-compliances have been found in all of them. DIPOA/SDA has assessed and approved their action plans, which are in progress.
08	Inspection personnel do not adequately enforce sanitation regulatory requirements to prevent the creation of insanitary conditions and direct product contamination.	As it has been stated in the FSIS/USDA Audit: "The FSIS auditors noted that the inspection and establishment records were generally representative of the actual sanitary conditions of the establishment.". Therefore, this finding's conclusion is not grounded. The non-compliances detected were isolated and have been corrected according to the establishments' individual action plans.
09	Inspection personnel do not accurately assess the design and implementation of the establishments HACCP systems, and do not conduct adequate verification sampling of products.	The verification of the written HACCP plan by the local official service is defined in DIPOA Internal Standards (Norma Interna) 01/2017 and the verification of the supervision activities is defined in DIPOA Internal Standards (Norma Interna) 02/2017. According to the FSIS auditors, the conclusion for item VII of the Mission Report was based on the following: a) The absence of documentation to provide basis for the hazard analysis, in one establishment, to guarantee the safety of water used in the production processes; b) The non-compliance in the sampling procedure for STEC testing in one establishment (it considered the weight instead of the number of pieces); and c) the lack of randomized official sampling for STEC testing. Those three findings do not support the conclusion of the FSIS auditors. Hazard analysis may be determined in the regulations or based on scientific basis. The monitoring of water quality in the establishments eligible to export to the United States is defined by a legislation, that is, it is compulsory according to Memorandum 34/2016/CGI/DIPOA, of April 22, 2016, and item 2 of Memorandum 52/2017/CGCOA/DIPOA, of April 10, 2017. We highlight that the quality parameters have been updated in the Memorandum n° 53/2017/CGCOA/DIPOA, of April 12, 2017. Regarding the non-compliance found in the sampling procedure of the establishment regarding STEC testing, the finding was isolated and has been corrected according to the corrective measures of SIF 4400 establishment. The randomized official sampling for STEC testing was defined by Topic 5 of the Manual for Sampling of Animal Products published in July 2017 and submitted by Memorandum n° 22/2017/CGPE/DIPOA, of July 13, 2017.
10	The official methods of chemical analysis used by the government laboratories is inconsistent with FSIS requirements.	Although the finding states "chemical analysis", the non-compliance regards microbiological tests. This non-compliance was isolated and has been immediately corrected. The local official service in one establishment was sending the beef jerky samples for microbiological testing to an inappropriate official laboratory. The Official Service has been instructed regarding the correct laboratory and three official samples have been taken at that moment with numbers SIF226/RS/061, 062 and 063/2017. The attached results are compliant with the legislation in force.
11	The CCA has not instructed establishments and in-plant inspectors to hold livestock carcasses selected for residue sampling until acceptable results are received.	As it has been discussed during the opening and exit meetings of the Veterinary Mission, it has been clarified that Brazil does not have the test kits for an immediate result.

		The purpose of the samples taken by the Official Service for the sampling defined by the National Plan for the Control of Residues and Contaminants - PNCRC is to perform the official verification on the production chain. In this phase of the Plan, sampling of matrices (liver, kidney, muscle, etc.) does not imply carcass detention until the test results are received. When the samples are violated, an official investigation process is started and includes the slaughterhouse and the farm of origin of those animals (to evaluate handling and inputs used). In this phase of the investigation, five consecutive lots from the same farm owner and from the same farm are officially sampled and their respective carcasses are detained until the results are received for official assessment. The result of the investigation determines comprehensive actions on the production chain and not only on the monitored carcasses. The investigation procedure is defined in Ordinance (Portaria) SDA/MAPA n° 396 of November 23, 2009. Finally, we clarify that the detection of violations that pose risk to public health determines the adoption of the necessary actions to recall all lots of products involved as per the sole paragraph of Article 81 of Decree 9,103 enacted on March 29, 2017.