USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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DEC 19 2019

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

Dear Dr. Leite Ribeiro,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Brazil's meat inspection system from June 10 through June 28, 2019. Enclosed is a copy of the final audit report. The comments and corrective actions received from the Government of Brazil are included as an attachment to the report.

As indicated in our November 22, 2019, letter to your government, FSIS plans to conduct a targeted on-site verification audit in order to verify Brazil's implementation of specific corrective actions related to the findings listed below. Based on the written documentation provided by the Ministry of Agriculture, Livestock and Food Supply (MAPA), FSIS believes Brazil's meat inspection system is meeting U.S. import requirements. However, the audit is critical to verify full implementation of the written controls within your country's meat inspection system.

- The implementation of written guidelines that prescribe the body temperature at which livestock (i.e., beef cattle and swine) are to be condemned during ante-mortem inspection.

- The implemented post-mortem inspection procedures to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection.

- The control of specified risk material, which includes (1) preventing contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, (2) appropriate trimming of lingual tonsils, and (3) documenting the removal of dorsal root ganglia and vertebral column at deboning.

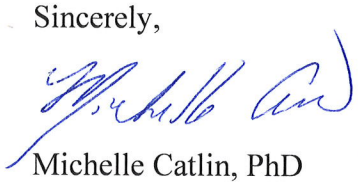
- The operation and maintenance of retorts, including accurate retort temperature recording, proper operations to ensure compliance with validated process schedules, design of retorts (e.g., proper bleeder placement), and implementation of official verification activities to ensure a hands-on or direct observation component.

- The direct access by the regional Inspection Service of Products of Animal Origin (SIPOA) offices to all official microbiological testing results provided by testing laboratories.

- The design and implementation of N-60 sampling for Shiga toxin-producing *Escherichia coli* (STEC) by government inspectors and testing of these samples by the government laboratories.

We appreciate MAPA's continued engagement to resolve these issues and support for the targeted on-site verification audit in January. If you have any questions, please contact the Office of International Coordination by email at InternationalCoordination@usda.gov.

Sincerely,



Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN BRAZIL

JUNE 10 - 28, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING RAW AND PROCESSED MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

December 13, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from June 10 through 28, 2019. The purpose of the audit was to determine whether Brazil's food safety inspection system governing raw pork and processed meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. An additional objective was to assess the regulatory oversight that the government provides to the inspection system to determine if controls are in place to reinstate raw beef imports from Brazil. This included verification of USDA's Animal and Plant Health Inspection Service (APHIS) requirements set forth in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.29 for the control of foot and mouth disease (FMD). Brazil currently exports processed beef and pork and raw intact pork to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors identified the following findings in two of the six components:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection at three of the seven audited beef slaughter and processing establishments.
- The Central Competent Authority (CCA) does not maintain written guidelines that prescribe the body temperature at which livestock (i.e., beef cattle and swine) are to be condemned during ante-mortem inspection.
- The FSIS auditors identified deficiencies at five of the seven audited beef slaughter and processing establishments related to the control of specified risk material (SRM). These included the potential for contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, inadequate trimming of lingual tonsils, and failure to document the removal of dorsal root ganglia and vertebral column at deboning.
- The FSIS auditors identified concerns in meeting the APHIS requirements outlined in 9 CFR 94.29 regarding carcass maturation. This included the use of a set of inaccurate pH meters at one establishment, as well as the inability for all audited establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i).

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The two audited government laboratories are not analyzing the entire N-60 sample if the sample submission is greater than the size of the test portion prescribed by the screening method (325 g ±10 %).
- The FSIS auditors identified deficiencies related to the verification of operation and maintenance of retorts at three of the four establishments preparing thermally processed, commercially sterile products, including deficiencies related to retort temperature recording at two establishments. The FSIS auditors also noted that official verification activities at two of these facilities only included a records review and did not include a hands-on or direct observation component.
- The regional Inspection Service of Products of Animal Origin (SIPOA) offices do not have direct access to all official microbiological testing results provided by testing laboratories.
- At the single audited swine slaughter and processing establishment, the establishment personnel were using the m/M criteria to analyze the generic *E. coli* results from samples collected using the carcass sponge technique. However, the use of the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method.

Prior to the audit's conclusion, the CCA demonstrated that it had instituted proper inspection procedures for post-mortem inspection and committed to address the remainder of the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided. FSIS has communicated the animal health findings related to the control of FMD to APHIS, which has committed to following-up on these issues.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Brazil's food safety system from June 10 - 28, 2019. The audit began with an entrance meeting held on June 10, 2019, in Brasília, Distrito Federal, Brazil, during which the FSIS team discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Department of Inspection for Products of Animal Origin (DIPOA) in the Ministry of Agriculture, Livestock and Food Supply (MAPA). Representatives from the CCA accompanied the FSIS team throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This equivalence verification audit presented two primary objectives. The first audit objective was to determine whether the food safety system governing raw pork and processed beef and pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged (ongoing equivalence). The second objective was to assess the regulatory oversight that the government provides to the raw beef inspection system to determine if controls are in place to reinstate raw beef imports from Brazil (i.e., equivalence reinstatement). This included verification of USDA's Animal and Plant Health Inspection Service (APHIS) requirements set forth in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.29 for the control of foot and mouth disease (FMD). Brazil is currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1],[2]
Raw - Non Intact	Raw non-intact pork	Ground product; other non-intact; and sausage.
Raw - Intact	Raw intact pork	Boneless manufacturing trimmings; carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals.
Thermally Processed - Commercially Sterile	Thermally processed, commercially sterile (beef, goat, lamb, mutton, pork, and veal)	Corned (species); ham; other; sausage; and soups.
Heat Treated - Shelf Stable	NRTE otherwise processed meat (beef,	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils;

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.
[2] On June 22, 2017, FSIS suspended the eligibility of imports of all raw intact beef products from Brazil.

	goat, lamb, mutton, pork, and veal)	sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.
Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking) (beef, goat, lamb, mutton, pork, and veal)	Other - not sliced; other - sliced; sausage/salami - not sliced; and sausage/salami - sliced.
Heat Treated - Shelf Stable	RTE dried meat (beef, goat, lamb, mutton, pork, and veal)	Ham - not sliced; ham - sliced; jerky; other - not sliced; and other - sliced.
Fully Cooked - Not Shelf Stable	RTE fully-cooked meat (beef, goat, lamb, mutton, pork, and veal)	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Fully Cooked - Not Shelf Stable	RTE meat fully cooked without subsequent exposure to the environment (beef, goat, lamb, mutton, pork, and veal)	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.

APHIS recognizes that beef imported from Brazil is subjected to the bovine spongiform encephalopathy requirements specified in 9 CFR 94.18 and/or 9 CFR 94.19. In addition, Brazil is affected with FMD, except in the State of Santa Catarina, and is subjected to animal health requirements in 9 CFR 94.4; however, fresh (chilled or frozen) beef imported from the States of Bahia, Distrito Federal, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio Grande do Sul, Rio de Janeiro, Rondônia, São Paulo, Sergipe, and Tocantins is subjected to animal health requirements specified in 9 CFR 94.11 and 94.29. Pork imported from Brazil is subjected to African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.32, and swine vesicular disease requirements specified in 9 CFR 94.13.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Brazil's SRT responses and supporting documentation. The FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Brazil's food safety inspection system governing raw and processed meat is being implemented as documented in the country's SRT responses and supporting documentation.
FSIS applied a risk-based procedure that included analyses of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, United States point-of-entry (POE) reinspection and 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 the self-reporting tool (SRT).

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 and 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, 4 regional inspection offices, and 11 local inspection offices in the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. A sample of 11 establishments was selected from a total of 31 establishments certified to export to the United States. This included seven beef slaughter and processing establishments (five of which conduct only simple processing, i.e., fabrication), three beef processing establishments, and the sole pork slaughter and processing establishment eligible to export product to the United States.

During the establishment visits, the FSIS auditors paid attention to the extent at which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

Additionally, FSIS audited two government laboratories that conduct chemical and microbiological analyses to verify the adequacy of the technical support they provide to the inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Department of Inspection for Products of Animal Origin (DIPOA), Brasília, Distrito Federal
	Regional Inspection Offices	4	• Inspection Service of Products of Animal Origin (SIPOA) offices: – Rio Grande do Sul, Porto Alegre – Goiás, Goiânia – São Paulo, São Paulo – Santa Catarina, Florianópolis
Laboratories		2	• Laboratórios Federais de Defesa Agropecuária (LFDA), government microbiological and chemical testing laboratories: – LFDA São Paulo, Campinas – LFDA Minas Gerais, Pedro Leopoldo
Beef slaughter and fabrication establishments		5	• Establishment SIF 431, Palmeira de Goiás, Goiás • Establishment SIF 504, Ituiutaba, Minas Gerais

		• Establishment SIF 1662, Campo Grande, Mato Grosso do Sul • Establishment SIF 4238, Bataguassu, São Paulo • Establishment SIF 4400, Campo Grande, Mato Grosso do Sul
Beef slaughter, fabrication, and processing establishments	2	• Establishment SIF 385, Andradina, São Paulo • Establishment SIF 2543, Promissão, São Paulo
Beef processing establishments	3	• Establishment SIF 226, Hulha Negra, Rio Grande do Sul • Establishment SIF 337, Lins, São Paulo • Establishment SIF 421, Barretos, São Paulo
Pork slaughter and fabrication establishment	1	• Establishment SIF 3548, Chapecó, Santa Catarina

FSIS performed the audit to verify Brazil's food safety inspection system met requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Brazil's inspection system for raw and processed beef and pork products 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 *Agreement on the Application of Sanitary and Phytosanitary Measures*.

III. BACKGROUND

From February 1, 2016 to January 31, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 266,028,201 pounds of meat from Brazil. This included 122,112,534 pounds of thermally processed, commercially sterile (TPCS) beef; 660,254 pounds of ready-to-eat (RTE) beef fully-cooked without subsequent exposure to the environment; 18,734,723 pounds of RTE fully-cooked beef; 60,555,534 pounds of RTE dried beef; 51,999 pounds of RTE acidified/fermented beef (without cooking); 20,930,270 pounds of raw intact beef (prior to suspension in June 2017 by FSIS); 572,773 pounds of not ready-to-eat (NRTE) otherwise processed beef; 113,946 pounds of TPCS pork; and 42,296,168 pounds of raw intact pork exported by Brazil to the United States.

Of these amounts, additional types of inspection were performed on 149,511,817 pounds of meat, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, O121, and O145 in beef; and *Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). On March 18, 2017, FSIS implemented increased product exams and sampling and testing for pathogens of all meat products imported from Brazil to ensure ongoing equivalence in response to a serious trend of

food safety violations identified at port-of-entry (POE) during reinspection of Brazilian product. FSIS conducted the last audit of Brazil in May 2017.

On June 22, 2017, FSIS suspended the eligibility of raw intact beef from Brazil. FSIS took the action to protect United States public health in response to a serious trend of food safety violations and animal health concerns (i.e., the presence of tissues prohibited by APHIS, such as blood clots, lymph nodes, and bone fragments) identified at point-of-entry (POE) during reinspection of Brazilian product. These POE violations correlate to observations made during the last onsite audit of Brazil conducted in 2017, which included weaknesses in Brazil's government oversight of sanitation (product handling) and post-mortem carcass inspection; inadequate verification of sanitary dressing procedures; and lack of conflict of interest controls between inspection personnel and establishment management. The nature, extent and degree of 2017 audit findings has also played an equivalent role in FSIS' decision to elevate the frequency of product exam and other sampling and testing at POE discussed above.

Between March 18 and June 28, 2017, FSIS refused entry to approximately two million pounds of raw beef products due to public health and animal health concerns; mainly pathology defects (abscesses) and tissues prohibited by APHIS, including blood clots, bones, and lymphoid tissue. The following table summarizes food safety-related POE violations that have occurred since the 2017 audit.

Summary of Critical Lot Refusals (Since May 2017)

Establishment #	Refusal Description
SIF 226	• Four violations for TPCS beef (condition of containers) resulting in a total of 117,529 pounds of TPCS beef products refused entry.
SIF 337	• Two residue violations (doramectin, a dewormer) in cooked beef resulting in a total of 90,461 pounds refused entry. • Eight violations for TPCS beef (predominantly condition of containers) resulting in 391,959 pounds of TPCS products refused entry.
SIF 385	• One violation for TPCS beef (condition of container) resulting in 8,995 pounds of TPCS products refused entry.
SIF 3548	• Residue violation (doxycycline, an antibiotic) in raw intact pork resulting in 60,627 pounds of raw intact pork primals/subprimals refused entry.
SIF 4238	• STEC (O103) positive in raw beef trimmings resulting in 180 pounds of beef products refused entry, in accordance with the requirements specified in FSIS Notice 26-17 *"Sampling Imported Brazilian Raw Beef Product Assigned an E. coli MT51 Type of Inspection at an Increased Level of Reinspection"* issued on May 12, 2017.

In addition to the POE violations outlined above, establishments SIF 337, SIF 385, and SIF 421 were subject to United States consumer complaints and notifications of receipt of adulterated product for the presence of foreign materials in cooked and canned beef products. Such foreign

materials included plastic, bone, and rubber. All establishments identified in this section were examined during the current FSIS audit.

The previous FSIS audit of Brazil in 2017 identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The CCA had 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 did not verify that regulatory information provided to supervisory official veterinarians is consistently communicated to their subordinates;
- The CCA did not verify that in-plant inspectors perform their assigned duties in a manner that is consistent with the issued instructions; and
- The CCA had not developed procedures to standardize the assessment of competence and performance of in-plant inspection personnel assigned to establishments certified to export to the United States.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects receive the mark of inspection;
- Brazilian TPCS product re-inspected at United States POE demonstrated 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 did not adequately enforce sanitation regulatory requirements to prevent the creation of insanitary conditions and direct product contamination.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

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

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

As stated previously, these findings and concurrent POE violations resulted in FSIS suspending raw beef from Brazil in June 2017. Since that time, FSIS has conducted numerous document

reviews and held technical meetings with the purpose of ensuring that practical, long-term solutions have been implemented by the CCA to address concerns with government oversight of the Brazilian meat industry. The current audit included visits to seven establishments identified as providers of raw beef source materials to several processing establishments throughout Brazil which actively export to the United States. The FSIS auditors verified implementation of the corrective actions for the specific previously reported audit findings and POE violations.

The FSIS final audit reports for Brazil's food safety inspection system are available on the FSIS website at: https://www.fsis.usda.gov/foreign-audit-reports.

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 food safety 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 confirmed that DIPOA, a department within MAPA, continues to serve as the CCA for Brazil's meat inspection system. In late 2017, DIPOA underwent restructuring, and Articles 117 through 154 of *Ordinance No. 562/2018* (*Internal Regulation of the Secretariat of Animal and Plant Health*) presents the new structure of DIPOA and attributes of each sector responsible for the inspection of animal products. Notably, Article 117 of *Ordinance No. 562/2018* ensures that DIPOA provides sanitary inspection and oversight of animal products, and Article 141 identifies the regional Inspection Service of Products of Animal Origin (SIPOA) as responsible for scheduling, executing, monitoring, and evaluating inspection and oversight activities of animal products including activities conducted by the Federal Inspection Service (SIF).

Three organizations within DIPOA are responsible for ensuring uniform implementation of inspection activities at establishments certified to export to the United States: the General Coordination for Special Programs (CGPE), the General Coordination for Inspection (CGI), and the General Coordination of Control and Evaluation (CGCOA). Ten decentralized SIPOA units, located in regions established by DIPOA, perform oversight and follow-up of the inspection performed by the SIF. Inspection at the local level is conducted by the SIF team located in each establishment registered with DIPOA. The SIF team is headed by an official veterinarian who is supported by online inspection staff consisting of inspection agents and inspection auxiliaries. The SIF has the responsibility and authority to implement and enforce inspection laws at the establishment level. DIPOA maintains oversight of the SIPOA units through the Division for National Audits (DIAN). Additionally, DIPOA maintains oversight over the SIF (local inspection) through the Department of Audits in Establishments (DAE) and Service for Audits in Establishments (SAE).

Brazil's meat inspection system is governed by and implemented through decrees, ordinances, and normative instructions that establishments must follow. Memorandums and circulars contain instructions specific for inspection personnel. *Decree No. 9,013/2017* is the overarching legislation for MAPA and includes sanitary and operational requirements applicable to all Brazilian establishments involved in agricultural processes. *Norma Interna No. 1/2017* includes government verification activities for the SIF to ensure all establishments, including those certified to export meat to the United States, comply with Brazilian laws, DIPOA policies, and requirements developed through bilateral or multilateral agreements. Additionally, *Memorandum No. 52/2017* establishes specific government verification activities at establishments certified to export to the United States.

DIPOA has the authority to certify and decertify establishments for eligibility to export to the United States. Additionally, DIPOA maintains a certification program for SIF inspection personnel to verify shipments destined to the United States meet import requirements. *Circular Letter No. 15/2019* mandates that official meat inspection certificates for meat food products cannot be issued unless the laboratory test results are compliant with FSIS requirements for livestock carcasses that have been tested for veterinary residues and meat products that have been tested for pathogens, including *Lm*, *Salmonella*, and STEC. This includes results from official testing by the CCA and self-monitoring by establishments. Through direct observation in conjunction with document reviews, the FSIS auditors verified the certification process conducted by the SIF, which included the review of all production records for acceptability and compliance, from ante-mortem inspection to the certified establishment's pre-shipment review. Additionally, the FSIS auditors verified that establishments certified to export to the United States maintain recall plans in accordance with *Circular Letter No. 41/2010*.

The FSIS auditors verified that Brazil's inspection system ensures source materials used in the production of meat products eligible to export to the United States originate only from establishments certified as eligible. Intra-country shipments of source material are sent to establishments certified to export to the United States accompanied by *National Health Certificates* (CSNs), which explicitly identify the eligible market(s). *Memorandum No. 75/2017* instructs SIF personnel, prior to production of product eligible for export to the United States, to verify that the eligible source is listed on the FSIS website and to verify that the CSN or other health certificate indicates the source materials comply with United States health requirements.

The Brazilian government maintains two primary information technology systems to support its inspection system as it relates to the export of product to the United States. The first, the Electronic Information System (SEI), is used throughout MAPA on an administrative level. The second, the General Information System for SIF (SIG-SIF), is operational in nature and used by DIPOA to support daily inspection-related activities. When FSIS issues new requirements, DIPOA transmits this information to inspection personnel through the SIG-SIF system in the form of Memorandums or Notices. The information is also posted to MAPA's website. The government officials at the SIPOA offices demonstrated to the FSIS auditors how SIG-SIF is used to communicate with inspection personnel. SIG-SIF displays general information on the main "bulletin board" and information specific to the SIF is provided in a dedicated section. Both systems maintain the necessary security protocols to ensure that only authorized users can gain access.

The FSIS auditors verified that official personnel conduct ante-mortem inspection of all animals and online post-mortem inspection of every carcass and all parts and once per shift inspection verification during deboning and processing operations. In the plants, Official Veterinarians are assisted by Inspection Agents and Inspection Auxiliaries. In establishments certified to export to the United States, these positions are employed by the Brazilian government at the federal, state, and municipal levels. Staffing information is maintained in SIG-SIF and DIPOA verifies the employment link during the DIAN and DAE audits (as described on page 7). While visiting the establishments certified to export to the United States and during the audit of the SIPOA regional offices, the FSIS auditors verified the documented employment link, payment, and control of the state and municipal employees.

The FSIS auditors paid special attention to how MAPA and DIPOA addressed issues concerning conflicts of interest identified during the previous FSIS audit. In 2018, MAPA promulgated *Ordinance No. 249*, which contains the *Code of Ethical Conduct of Public Officials of the Ministry of Agriculture, Livestock and Food Supply – MAPA* in the Appendix. This code supplements the professional ethics requirements contained in the *Code of Professional Ethics of Civil Public Officials of the Executive Branch* and the *Code of Conduct for Higher Spheres of the Federal Administration*.

This *Ordinance* requires employees to consult the Ethics Committee of the MAPA (CE/MAPA) or the Digital Conflict of Interest System (Sistema Eletrônico de Conflito de Interesses—SeCI) on the existence of conflicts of interest and request authorization to conduct private activities in accordance with *Law No. 12,813/2013*. Such consultations on the existence of a conflict of interest may result in disciplinary action to include dismissal from public service. Additionally, the *Ordinance* contains information on the types of actions by MAPA officials that are prohibited, and expressly forbids MAPA employees from involving themselves in situations arising to conflicts regardless of whether there is harm to the public good. In 2019, DIPOA has been conducting one-week trainings for all SIF establishment personnel and there is a specific module covering ethics and conflicts of interest.

The FSIS auditors conducted interviews and document reviews at headquarters and SIPOA offices to assess requirements for minimum education, hiring, and training of government inspection staff deployed at certified establishments. The minimum requirement for a veterinarian to be assigned at SIF establishments is Doctor of Veterinary Medicine or an equivalent degree. For other online and support inspection staff, the employees must possess a high school diploma to be eligible to apply for an inspector's position in government. All new entrants, irrespective of positions as veterinarians, inspector agents, or auxiliaries, receive initial in-class and on-the-job training. DIPOA routinely organizes the training for inspection staff on FSIS import requirements.

DIPOA is responsible for direct oversight of government laboratories that conduct chemical and microbiological testing of meat products exported to the United States. The General Coordination for Laboratory Support (CGAL) is the agency within DIPOA responsible for certifying official and accredited laboratories (*Norma Interna No. 57/2013*) and for validating the analytical methods to be employed by the laboratories. Thus, only laboratories in compliance

with CGAL standards are authorized to carry out official analyses. Both government-owned and privately-owned laboratories carry out analysis of official samples and are considered part of Laboratórios Federais de Defesa Agropecuária (LFDA). Private laboratories must be approved by the DIPOA and CGAL and are subject to audit by the CGAL twice per year.

The FSIS auditors visited two LFDA government testing laboratories in Campinas and Pedro Leopoldo accredited by the General Coordination for Accreditation of National Institute of Metrology, Standardization and Industrial Quality (INMETRO) to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration of laboratories*, standards. Both chemical and microbiological testing laboratories receive accreditation audits by the INMETRO accrediting body. In addition to accreditation audits of the laboratories, DIPOA also conducts audits of LFDA laboratories.

While DIPOA has instituted programs to identify potential conflicts of interest and harmonize inspection activities from a central level for both SIF units (DAE audits) and SIPOA offices (DIAN audits), the FSIS auditors identified systemic deficiencies related to the enforcement of inspection system requirements for ante-mortem and post-mortem inspection; control over condemned materials; government microbiological testing; and maintenance and operation of retorts. The nature of these deficiencies indicates a need for DIPOA to continue to strengthen its oversight of its meat inspection system.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND 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 and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; and periodic supervisory visits to official establishments.

Decree No. 9,013/2017 requires Brazilian establishments to develop self-control procedures for animal welfare in accordance with specific requirements concerning establishment facilities, livestock handling (including during transport and unloading), access to feed and water, stunning, and sticking at slaughter facilities. During the site visits of slaughter facilities, the FSIS auditors observed the SIF inspection personnel verifying the establishments' compliance with humane handling requirements.

Decree No. 9,013/2017 contains general requirements concerning ante-mortem and post-mortem inspections at slaughter establishments. *Ordinance No. 711/1995* contains specific procedures for ante-mortem and post-mortem inspections of swine animals and the *Manual for Beef Inspection* contains specific procedures for ante-mortem and post-mortem inspections for bovine animals.

The FSIS auditors verified that an in-plant official veterinarian conducts ante-mortem inspection on the day of slaughter, including review of incoming registration and identification documents. Brazilian ante-mortem inspection procedures require the SIF veterinarian to observe the animals just prior to slaughter at rest and in motion from both sides (although an isolated finding regarding this procedure was identified at one location). Each establishment has a designated observation pen for further examination of suspect animals.

The FSIS auditors confirmed by direct observation and review of records that SIF veterinarians conduct ante-mortem inspection of all animals prior to slaughter. The FSIS auditors, however, noted that there is no specific standard within Brazil's inspection system that prescribes the body temperature at which livestock should be condemned during ante-mortem inspection. Discussions with inspection personnel regarding condemnation at ante-mortem inspection resulted in a range of temperatures being referenced, some of which were not consistent with values considered relevant by the veterinary scientific community. Consequently, inspection personnel need to be provided with further guidance to ensure that livestock exhibiting high temperatures at ante-mortem inspection be excluded from export to the United States in a manner equivalent with the requirements outlined in 9 CFR 309.3 (e.g., >105° F for cattle).

- The Central Competent Authority (CCA) does not maintain written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection.

DIPOA ensures that each and every livestock carcass, parts (from further processing of carcasses), and offal are inspected by a government inspector after slaughter at standardized locations on the lines. Judgements concerning the dispositions of carcasses, parts, and organs are the duty of the SIF veterinarian. In addition to authorizing post-mortem inspections, *Decree No. 9,013/2017* authorizes SIF personnel to stop or reduce slaughter line speeds whenever necessary, including when deficiencies are identified.

FSIS assessed post-mortem examinations through on-site record review, interviews, and observations of inspection activities in all audited slaughter establishments. The FSIS auditors observed and verified the presentation, identification, examination, and disposition of carcasses and parts to ensure proper implementation of post-mortem examinations. This included observation of the inspection personnel examining the heads, viscera, and carcasses. The FSIS auditors identified deficiencies related to the manner by which post-mortem inspection procedures were conducted in three of the seven audited bovine slaughter and processing establishments. This included concerns related to improper manual inspection techniques (i.e., failure to palpate kidneys at one facility); presentation of heads (i.e., removal of eyeballs before post-mortem inspection at one facility); removal of contamination (i.e., failure to identify bile on the internal carcass surface at one facility); and improper synchronization of heads, viscera, and carcasses at two facilities.
Furthermore, the FSIS auditors noted that the ink markings used to maintain synchronization between heads, viscera, and carcasses during post-mortem inspection were illegible at two audited facilities. Consequently, inspection personnel could not effectively identify which head corresponded to which viscera and carcass when asked by the FSIS auditors during the establishment tour. Synchronization between heads, viscera, and carcasses is important in ensuring that accurate assessment to the health status of the animal during post-mortem

inspection, especially when carcasses and associated viscera and heads are presented for additional veterinary review. Separated parts must remain identified with the corresponding carcass in order to ensure that when a carcass is condemned, the separated parts associated with that carcass are also condemned.

- The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection at three of the seven audited beef slaughter and processing establishments.

DIPOA ensures that a representative of the government inspection system makes periodic supervisory visits to each certified establishment with the purpose of evaluating the performance of inspection personnel. Prior to December 31, 2018, government supervisors from SIPOA conducted quarterly visits to establishments certified to export to the United States to evaluate the performance of the SIF unit. Partially in response to the 2017 FSIS audit findings, *Ordinance No. 562/2018* created a new audit division, the DAE, with the main purpose of establishing oversight of the SIPOA and SIF. MAPA established the DAE to standardize and centralize all audit procedures.

There are four SAE sections under the DAE, and the primary SAE is responsible for conducting audits in establishments certified to export products to the United States. Effective January 1, 2019, these audits occur at a minimum of once per year and replace the SIPOA quarterly reviews. The audits evaluate SIF oversight of the establishment, focusing on hygienic and technical conditions, and the DAE enters pre-audit, audit, and post-audit results in the SEI, which are accessible by the entire Ministry. MAPA justified the change in frequency due to the direct link between DIPOA and DAE. The frequency may be increased in establishments exhibiting issues associated with public health or overall underpinnings of certification. The FSIS auditors verified that establishments certified to export to the United States were subject to quarterly supervisory reviews by the SIPOA units up until December 31, 2018, and reviewed DAE audit results for 2019 in the establishments subject to DAE audits prior to the FSIS on-site audit.

DIPOA requires establishments to remove SRM, prohibits SRM for use in human and ruminant feed, prohibits the use of non-ambulatory disabled cattle for export to the United States, prohibits the use of stunning devices that inject air into the cranium, and requires government inspection personnel verify adequate identification, removal, and disposal of SRM once every 14 days. *Circular Letter No. 463/2004* and *Memorandum-Circular Letter No. 8/2017* define SRM as equivalent to the United States domestic system to include: brain, skull, eyes, trigeminal ganglion, spinal cord, spinal ganglia roots, spinal column (excluding the caudal vertebrae, the transversal processes of the thoracic and lumbar vertebrae, and sacral wings) of bovine animals thirty months of age and older, and the tonsils and the distal portion of the ileum for bovine animals of all ages.

The FSIS auditors' review of documents *Circular Letter No. 463/2004* and *Memorandum-Circular Letter No. 8/2017* noted that both had incorrectly defined the distal ileum as having a length of 70 centimeters contrary to 203.2 centimeters (80 inches) referenced in 9 CFR 310.22(d). The FSIS auditors observed that establishments were removing 203.2 centimeters, having included this latter value into their written programs. *Memorandum-Circular Letter No.*

1/2007, *Circular Letter No. 622/2014*, and *Circular Letter No. 66/2015* contain additional guidelines for the removal, segregation, and disposal of SRM in accordance with DIPOA requirements.

The FSIS auditors verified that beef slaughter establishments eligible to export to the United States have reviewed their SRM control programs in accordance with the aforementioned documents. However, the FSIS auditors noted that four of the seven audited beef slaughter establishments did not institute measures to prevent leakage of brain tissue from the knock hole of cattle during head washing. However, no direct contamination by brain tissue was observed by the FSIS auditors during the head washing and head/cheek meat harvesting process.

All cattle slaughtered were handled as though they were thirty months of age or older within the context of the establishment's written control program for SRM. Therefore, brain tissue from all slaughtered animals is to be considered SRM. These establishments harvest cheek meat and head meat for potential use as raw material in TPCS or fully cooked RTE products destined for export to the United States. Furthermore, the FSIS auditors identified deficiencies related to the removal of lingual tonsils (one establishment) and documentation of removal of dorsal root ganglia and vertebral column (one establishment).

- The FSIS auditors identified deficiencies at five of the seven audited beef slaughter and processing establishments related to the control of specified risk material (SRM). These included the potential for contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, inadequate trimming of lingual tonsils, and failure to document the removal of dorsal root ganglia and vertebral column at deboning.

In accordance with an inter-agency agreement, the FSIS auditors verified the establishments certified to export to the United States' compliance with APHIS requirements codified in 9 CFR 94.29 for the control of FMD. The FSIS auditors confirmed that SIF inspection personnel examined the coronary band for each hoof as well as the lips and snout of each individual animal slaughtered. In addition, the FSIS auditors noted that establishment employees measured the pH for each half carcass after it had gone through the maturation chamber. However, the FSIS auditors identified two concerns associated with assuring adherence to these APHIS requirements.

The first concern relates to observation of the use of a set of inaccurate pH meters at one establishment, as the auditors observed that the pH meters did not measure the accurate pH of the calibration solutions after being calibrated. The second concern derived from discussions held with the government officials and inspection personnel, reflects a country-wide practice, where it was indicated that carcasses enter the maturation chamber on Friday, the pH would not be measured until Monday. This practice does not permit the establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i). FSIS has communicated these findings to APHIS, who has committed to following up on these issues. At this time, there are no establishments in Brazil eligible to export raw beef to the United States.

- The FSIS auditors identified concerns in meeting the APHIS requirements outlined in 9 CFR 94.29 regarding carcass maturation. This included the use of a set of inaccurate pH meters at one establishment, as well as the inability for all audited establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i).

Brazil's meat inspection system maintains the legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. However, deficiencies were identified related to the inspection officials' enforcement of regulatory requirements for ante-mortem inspection, post-mortem inspection, and controls over inedible materials, specifically SRM. In addition, DIPOA is requested to provide additional information regarding the controls on head and cheek meat originating from cattle at establishments which do not institute measures to prevent leakage of brain tissue from the knock hole of cattle during head washing.

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 sanitation standard operating procedures (SOPs) to prevent direct product contamination or insanitary conditions.

The FSIS auditors verified that DIPOA ensures that livestock are slaughtered and processed in a sanitary measure, to prevent carcass contamination with feces, ingesta, milk, bile, hair, dirt, or foreign material. *Decree No. 9,013/2017* contains requirements that establishments certified to export to the United States maintain facilities, equipment, and utensils in good hygienic conditions before, during, and after operations. Article 74 requires establishments to develop, implement, monitor, and maintain sanitation SOPs that prevent direct and cross-contamination of products prior to, during, and after operations. Additionally, this *Decree* requires establishments certified to export to the United States to incorporate slaughter controls in the self-monitoring programs and address conditions that would result in conditional use or condemnation of carcasses at slaughter.

DIPOA further supplements the *Decree* with prescriptive requirements for beef slaughter operations in the *Manual for Beef Slaughter* and for hog slaughter operations in *Ordinance No. 711/1995*. The FSIS auditors verified that the certified establishments maintained written procedures for sanitary slaughter operations, outlining specific measures taken at each slaughter step to prevent carcass contamination. It was further verified that both the establishments and SIF personnel monitor and verify, respectively, that these procedures are conducted at least once each shift.

During the visit to eight slaughter facilities (seven beef and one pork slaughter), the FSIS auditors directly observed the establishments employing sanitary dressing procedures. DIPOA requires establishments to slaughter and dress cattle in a sanitary manner to prevent carcass contamination with feces, ingesta, milk, bile, hair, dirt, or foreign material. For bovine slaughter, the cranial end of the esophagus must be tied with a strong surgical knot and the rectum must be

firmly tied with strong string prior to evisceration. For pork slaughter, it is required that the certified establishment tie the rectum prior to evisceration. If the gastrointestinal tract is pierced or burst, the SIF must condemn the contaminated viscera and rail out the affected carcass for further evaluation. DIPOA further requires inspection personnel to verify, through direct observation and records review, that establishments carry out sanitary dressing throughout slaughter process.

Norma Interna No. 01/2017 establishes frequencies and minimum sampling amounts to be used by the SIF for official verification of self-controls required of and developed by establishments certified to export to the United States. *Memorandum No. 52/2017* establishes that the official verifications performed by the SIF personnel in establishments certified to export to the United States shall follow *Norma Interna No. 01/2017*, but increases the frequencies of verification to daily, per shift for operational sanitary procedures (e.g., to verify sanitary dressing of livestock and general facility sanitation), operational sanitation SOPs, zero tolerance procedures, and other HACCP procedures. *Memorandum No. 52/2017* requires the SIF personnel to verify pre-operational sanitation SOPs once every two weeks. The FSIS auditors verified that the SIF personnel conducted verification activities in accordance with the procedures and frequencies established by *Norma Interna No. 01/2017* and *Memorandum No. 52/2017*.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at all audited establishments. The FSIS auditors verified the actual pre-operational inspection by shadowing and observing the in-plant inspector at one beef slaughter establishment conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspector's hands-on verification procedures begin after the establishment personnel conducted their pre-operational sanitation and determined that the facility is ready for government pre-operational sanitation verification activities. In-plant inspectors conduct this activity in accordance with the established procedures in *Norma Interna No. 01/2017*. The FSIS auditors followed the offline inspector and observed in-plant inspection verification of operational sanitation procedures at all audited establishments. These verification activities included direct observation of operations and review of the establishments' associated records.

In response to the findings of APHIS-prohibited tissues at the FSIS POE, DIPOA issued *Memorandum No. 85/2017*, which is specific for bovine slaughtering and deboning establishments. This *Memorandum* requires the government inspector to reinspect one percent but no less than ten quarters, of all beef quarters and one percent, but no less than ten pieces, of all boneless beef products destined for the United States per shift. Additionally, the *Memorandum* requires establishment employees to reinspect 100 percent of quarters to be deboned prior to entering deboning, five percent (based on the number of quarters to be deboned per shift) of cuts and trimmings prior to final packaging, and at least two bags of trimmings produced in the deboning room each working hour. The inspections must ensure that the quarters, cuts, and trimmings do not exhibit any prohibited tissues, defects, or contamination, such as lymph nodes, blood clots, bruises, bone, and foreign materials.

All establishments that export to the United States must comply with the provisions in the *Memorandum* and implement them in their self-control programs. The FSIS auditors verified by

records review and direct observation that the establishments certified to export to the United States conducting beef slaughter and deboning operations complied with the procedures and frequencies of *Memorandum No. 85/2017*. The FSIS auditors also verified that the SIF personnel verified the establishments' compliance with *Memorandum No. 85/2017*.

The FSIS auditors confirmed that Brazil's meat inspection system maintains regulatory requirements for all establishments certified to export to the United States to implement sanitation programs.

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

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

Ordinance No. 46/1998 requires that manufacturers of edible animal products utilize HACCP in establishments under SIF inspection. This ordinance provides establishments instructions for development, implementation, maintenance, and verification of HACCP systems. Establishment HACCP plans must be based on the seven principles of HACCP and founded on legal requirements (or upon scientific support when there is no legal requirement). Only those establishments having HACCP in place and implemented are eligible to engage in interstate commerce or listed for export in DIPOA.

The FSIS auditors verified through record review and observation that the in-plant inspection personnel at establishments certified to export to the United States conducted daily verification of implementation of HACCP plans. The in-plant inspection personnel verification of HACCP plans includes verification of critical control points (CCPs) for all production shifts in accordance *Norma Interna No. 01/2017* and *Memorandum No. 52/2017.*

At eight audited slaughter establishments, the FSIS auditors conducted an on-site review of the government-mandated zero tolerance (feces, ingesta, and milk) CCP records generated during the past year. In addition, the FSIS auditors reviewed the in-plant inspection's associated zero tolerance verification records at these locations. All establishments audited were conducting 100 percent monitoring of carcasses for this CCP. The review of the establishment's corrective actions in response to the few observed deviations from the zero tolerance critical limit indicated that all four parts of the corrective actions were correctly addressed. Furthermore, the FSIS auditors confirmed that the physical CCP monitoring location for government verification was before the final wash in all audited establishments.

Concerning the subset of beef slaughter establishments intending to export raw beef to the United States, the FSIS auditors noted that food business operators had addressed contamination of carcasses with STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121, and O145) within the context of their HACCP system. In addition to 100 percent monitoring of the zero tolerance CCP, additional control points typically employed by establishments included: chlorinated live animal washes; post-stun washing of the perianal region; use of steam vacuums; and sanitizing of

utensils between each carcass during bleeding, dehorning, skinning, and removal of udders. In addition to establishment controls, the FSIS auditors also noted that the CCA routinely verifies that establishments employ sanitary dressing procedures that prevent visible contamination.

All establishments producing 50,000 pounds or more of beef trimmings daily had developed a program to address high event periods (HEP), i.e., periods in which slaughter establishments experience a high rate of positive results for STEC (or virulence markers) in trim samples from production lots containing the same source materials. These programs included definitions for localized and systemic HEP which are based on the *FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers*.

At establishments producing frozen cooked beef, dried beef, and beef jerky, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. For frozen cooked beef, the FSIS auditors observed that all establishments had a CCP in place in order to meet Appendix I of *Memorandum No. 52/2017*, which requires that establishments certified to export cooked beef to the United States address the hazards of *Salmonella*, *Listeria monocytogenes*, and the FMD virus in the HACCP plans. In two of the three audited facilities that were producing dried beef and beef jerky, the establishments were following Appendix II of *Memorandum No. 52/2017* and included appropriate measures to address lethality, to include relative humidity within the cooking cycle, cooking temperature, and water activity. The FSIS auditors also reviewed the validation documents at these establishments, which indicated that the actual lethality achieved by these processes exceeded the minimum 6.5-$\log_{10}$ reduction for *Salmonella* prescribed in *Memorandum No. 52/2017*.

The audit results show that the CCA verifies that operators of official establishments implement the CCA's requirement to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditors' analysis determined that the CCA continues to demonstrate the ability to effectively implement and verify its regulatory requirements for those products that Brazil is currently eligible to export to the United States.

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 food safety inspection system is to 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.

FSIS' residue experts reviewed Brazil's monitoring program for 2018, 2017 results, associated methods of analysis, and additional SRT responses outlining the structure of Brazil's chemical residue testing program. The Brazilian *National Plan for Control of Residues in Products of Animal Origin* (PNCRC) was established by *Ministerial Decree No. 51*, of May 6, 1986, and by *Ministerial Decree No. 527*, of August 15, 1995. The PNCRC functions to control and conduct

surveillance of products for chemical residues. Its actions are aimed at understanding and preventing the violation of safety standards or maximum residue limits (MRLs) for allowed substances and the occurrence of residues and chemicals banned for use in the country at all levels. For this purpose, samples are collected from slaughtered animals and industrialized food products destined for human consumption originating from the establishments under federal (SIF) inspection.

The PNCRC has multiple subprograms, two of which are particular interest to FSIS as they specifically relate to the export of meat products to the United States from Brazil. The *Subprogram for Monitoring* aims at generating information on the frequency, level, and distribution of residues in the country, over time. The types of residues to be researched are selected based on potential risk and availability of analytical methodology appropriate to the goals of the monitoring being performed. The number of samples, the MRLs, the analytical methodology analyses, the matrices and the residues being analyzed, and the official and accredited laboratories are included in the annual schedule. The *Subprogram for Exploration* is used by DIPOA in special situations (e.g., in relation to United States export) to generate information about the frequency and levels where chemical residues occur in Brazil. To control avermectins in the exploratory subprogram, DIPOA determines eligibility for export based on the tolerances established by the United States Food and Drug Administration for avermectins, which includes 650 parts-per-billion in cattle muscle for ivermectin.

Since the last FSIS audit in 2017, three lots of Brazilian product were rejected for violative chemical residue levels at the United States' POE. This included two residue violations for doramectin (a dewormer) in cooked beef and one violation for doxycycline (an antibiotic) in raw intact pork. While on-site, the FSIS auditors were able to verify that the appropriate follow-up procedures were performed in conjunction with all violative chemical residue samples identified through implementation of the PNCRC since the last FSIS audit. The follow-ups performed by PNCRC included investigations of the farm(s) involved in the violations by way of on-site visits, document reviews, and interviews.

In some cases, the investigation extended to neighboring properties or other farms associated with the violative lot. Other actions included development of a corrective action plan, including preventive measures, by the violative SIF establishment and follow-up sampling of the next batches of animals originating from the farm involved in the infringement until the farm reached five consecutive conforming lots. Products from these lots were retained in the SIF establishment until the results of analysis were known. The SIF maintained records to demonstrate that the samples had been collected and tested accordingly. Additional action for non-compliant farms included withholding of *Animal Movement Permits* from the farms in question for a period of six months (for illegal drugs) or throughout the withdrawal period (for authorized drugs). Accordingly, DIPOA reports violations to the Department of Animal Health due to implications associated with animal movement permits.

The FSIS auditors visited two chemical residue testing laboratories, four SIPOA offices, and eight slaughter establishments to verify the adequacy of implementation of the PNCRC. A review of the sampling records maintained at the local inspection office of the audited slaughter establishments indicated that the 2019 sampling program was being adhered to as scheduled.

Residue samples for the monitoring program are collected by official inspection personnel as directed by the government's information technology system and are shipped under inspection seal to the laboratory in accordance with protocols issued by DIPOA. Through use of the information technology system, DIPOA tracks the samples and provides feedback to the in-plant inspection concerning adequacy of sample shipping and results of analyses. In accordance with *Circular Letter No. 15/2019*, DIPOA has adopted a hold and test procedure for carcasses and parts subject to sampling per its PNCRC to ensure product is not exported to the United States until acceptable results are obtained.

The FSIS auditors were presented with sufficient audit evidence while on-site (e.g., review of inspection records, presence of "veterinary retained" cages) to demonstrate that this policy was being effectively implemented. Additionally, during the evaluation of ante-mortem inspection at the eight audited slaughter establishments, the FSIS auditors observed that the official veterinarians verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods.

While reviewing the implementation of the corrective action proffered by the CCA in response to an audit finding in 2017, DIPOA officials informed the FSIS auditors that the residue analyses procedure had been revised approximately two weeks prior to the current audit. This revision was implemented to remove the practice of calculating the arithmetic mean of three samples analyzed successively. The change in testing procedure had been communicated to the network of laboratories via an e-mail message sent on May 30, 2019.

The FSIS auditors visited the LFDA government testing laboratories in Campinas and Pedro Leopoldo. These government laboratories are accredited by INMETRO to the ISO/IEC 17025 standards. The methods that the Campinas and Pedro Leopoldo LFDA use for detecting chemical residues are included in the laboratories' scopes of accreditation and determined equivalent by FSIS. The FSIS auditors verified that analysts assigned to the chemical residue laboratory have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation.

The result of the on-site audit activities indicate that Brazil continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues in veterinary drugs and chemical contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome. The FSIS auditors visited two government microbiological testing laboratories, four SIPOA offices, eight slaughter establishments (seven beef and one

pork), and three beef processing establishments to verify the implementation adequacy of the CCA's microbiological testing programs. Additionally, the review of this component also included Brazil's evaluation of inspection measures applied to thermally processed commercially sterile products exported to the United States.

The CCA conducts verification activities that monitor each establishment's generic *E. coli* testing program in chilled livestock carcasses. While on-site, the FSIS auditors verified that the responsible individuals presented the skills to implement this type of testing on an ongoing basis. Similarly, at the seven beef slaughter and processing establishments, both the establishment and inspection personnel are familiar with the upper and lower control limits, as well as the correct actions to be taken when the upper limits are exceeded. However, the FSIS auditors identified a discrepancy in the Brazilian requirements related to the evaluation of generic *E. coli* sponging results in swine carcasses.

Circular Letter No. 273/97/DIPOA indicates that results for generic *E. coli* testing are evaluated using statistical process control, but *Circular Letter No. 682/2012/CGPE/DIPOA* includes alternative criteria for swine. These alternative criteria are similar to those values outlined in 9 CFR 310.25 and used by FSIS domestically for the interpretation of testing results collected through the excision (not sponging) method. Establishments employing swabbing to sample carcasses are to employ statistical process control techniques for the interpretation of test results. Brazil has not received an equivalence determination to permit the use of excision criteria for the evaluation of swine carcass testing results using the excision method.

- At the single audited swine slaughter and processing facility, the establishment was using m/M criteria to analyze the generic *E. coli* results from samples collected using the carcass sponge technique. However, the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method.

The CCA has a *Salmonella* sampling and testing program for chilled livestock (cattle and swine) carcasses that is consistent with the FSIS *Salmonella* performance standards in 9 CFR 310.25(b). The CCA requires that one *Salmonella* set be scheduled per year. For bovine, a set consists of 82 carcass samples with one positive sample considered acceptable. For swine, a set consists of 55 carcass samples and up to six positive samples considered acceptable. An establishment exceeding the number of acceptable *Salmonella* positives in its first set must take immediate corrective action and reassess its HACCP plan, after which a second set of samples is collected. If the establishment fails to meet the performance standard on the second sample set, then the HACCP plan is audited by the Brazilian inspection service, and another sample set is collected. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States. The suspension would remain in effect until the establishment achieves the performance standard set based on number of samples tested (n) and maximum number of positives to achieve standard (c).

Brazil has an equivalence determination in place for *Salmonella* testing which permits establishment employees to collect the samples and for samples to be analyzed in private laboratories. In order to ensure that the food safety measures and objectives associated with this equivalence determination continue to be met, the FSIS auditors verified the implementation of

this program, and no concerns were identified. The FSIS auditors observed establishment employees collecting carcass samples at one beef slaughter establishment and official inspection personnel collecting carcass samples at two other beef slaughter facilities.

The FSIS auditors verified documentation that DIPOA schedules each *Salmonella* sample series. The SIPOA offices are responsible for informing local inspection personnel at SIF establishments when sampling is to begin and end, and for monitoring of the results. SIF inspection personnel randomly select carcasses on the morning the sample is to be collected, with no prior notification to the establishment. SIF inspection personnel observe the collection of each sample taken by establishment personnel, as well as measures related to sample integrity and security. Approved laboratories use FSIS Microbiological Laboratory Guidebook (MLG) Chapter 4C.08 for *Salmonella* analyses and are in process of implementing the current revision (MLG Chapter 4.10).

According to *Circular Letter No. 7/2019,* DIPOA stipulates a zero tolerance policy for STEC in raw beef products exported to the United States. For the purposes of manufacturing raw beef for United States export, item 3 of *Memorandum No. 62/2016* and item 21 of *Circular Letter No. 7/2019* require only "complete cycle" establishments inspected by the official inspection service as eligible. "Complete cycle" establishments are establishments that conduct slaughter, deboning, and storage. Receipt of source materials from outside establishments for raw beef manufacture is prohibited. The batch of raw beef cannot be composed of different source materials, which purports to reduce the risks of cross-contamination. *Circular Letter No. 7/2019* requires the establishments certified to export to the United States to identify the definition of a lot in their self-control programs.

The FSIS auditors verified that each of the audited establishments maintained written programs to define each production lot (should actual export to the United States begin to occur) as outlined in *Circular Letter No. 7/2019*. The inclusion of lot identity, independence, availability for inspection and testing, and traceability from origin to distribution in establishments programs were verified during the onsite audit and no concerns were identified.

Government inspectors conduct verification sampling for STEC and *Salmonella* at a minimum frequency of once per month for beef trimmings. The official samples are sent to laboratories within the LFDA and prepared in accordance with the N-60 technique described in *Norma Interna No. 01/2017* and subsequent DIPOA instructions. However, the FSIS auditors noted that samples collected were typically far greater than the anticipated 325 grams and observed the collection of a government sample weighing 830 grams at one establishment. At both the Campinas and Pedro Leopoldo facilities the FSIS auditors noted that during the on-site audit that laboratory personnel may not be analyzing the entire N-60 beef trim sample as received from establishments. Laboratory personnel at both facilities reported routinely weighing and analyzing a 325-gram test portion, even if the weighed test portion did not include all 60 pieces of trim from the N-60 sample.

- The two audited government laboratories are not analyzing the entire N-60 sample if the sample submission is greater than the size of the test portion prescribed by the screening method (325 g ±10%).

Beef slaughter establishments are required to sample and test 100 percent of lots destined for export to the United States for STEC and *Salmonella* per *Circular Letter No. 60/2015* and Item 1 in Appendix I of *Circular Letter No. 7/2019.* DIPOA requires establishments to hold lots of tested raw beef pending laboratory results, whether conducted by inspection personnel for verification purposes or as part of an establishment's self-control program. Establishments must also include the hold and test procedures in their self-control programs. Government inspectors review establishment testing records as required by *Circular Letter No. 7/2019* and *Norma Interna No. 01/2017*. The verification includes ensuring that the establishment is taking suitable corrective and preventive measures when necessary.

The FSIS auditors reviewed the corrective actions organized by the CCA in association with a POE violation for STEC which occurred in the summer of 2017. It was verified that no additional positive results for STEC were identified, either as a result of establishment or government testing, in recent history at any of the audited facilities. The government enforcement strategy ensured proper disposition of product: cooking, in this case. The government enforcement strategy reflected an intensified approach, which included the establishment's reassessment of its HACCP system and additional government product testing. The establishment also installed additional lighting at inspection points on the slaughter line and began implementing a steam vacuum at three separate points on the slaughter line.

The CCA has a verification testing program in place to test for *Lm* and *Salmonella* in RTE products that are eligible to be exported to the United States. The FSIS auditors noted that the laboratories use the FSIS MLG methods for the detection of *Salmonella* (MLG 4C.08) and *Lm* (MLG 8.11) on identical test portions used by FSIS, i.e., 325 grams for *Salmonella* and 25 grams for *Lm*. *Circular Letter No. 15/2019* permits the export of RTE products only if the laboratory results are negative (for both establishment and government testing). *Memorandum No. 52/2017* contains RTE sampling and inspection verification instructions for government personnel in establishments certified to export to the United States. During official verification, the government inspectors assess the certified establishment's control of *Listeria* via sanitation, prerequisite programs, process control records, and the *Listeria* Sentinel Program. The establishments certified to export to the United States identify surfaces in direct and indirect contact with the product and design the routine sampling for *Listeria* species.

Circular Letter No. 68/2015 requires the SIF team to collect one food contact surface (FCS) sample per month for each category of RTE product (frozen cooked beef and dried beef/beef jerky) to be analyzed for *Lm*. The CCA also mandates establishments to take five samples (three FCSs and two non-food contact surfaces) per production line per week to be analyzed for *Lm*. Sample sponges are collected using a 30x30 centimeter template. All samples are collected under observation by inspection personnel and sent in a secured package to a CCA-approved laboratory for analysis. Government inspectors collect monthly product samples of cooked frozen meat and bimonthly samples of dried beef products to be analyzed for *Salmonella* and *Lm*.

While verifying government testing results for FCSs, the FSIS auditors noted that SIPOA offices do not have direct access to all official microbiological testing results provided by the testing laboratories. Only positive (unacceptable) results are reported directly to SIPOA from the testing

laboratory. Both positive and negative official testing results are sent to inspection personnel at the originating establishment. The local inspection staff is then responsible for providing the SIPOA office with a compiled table of all the testing results (but not the actual laboratory reports). This lack of direct access to all laboratory reports can impact the SIPOA office's ability to verify: (1) the accuracy of the compiled tables of results provided by the local SIF inspection staff; (2) whether only approved methods are being used by the official laboratories; and (3) whether the appropriate target organisms are included in analyses, e.g., *Lm* versus *Listeria* species.

- The SIPOA offices do not have direct access to all official microbiological testing results provided by testing laboratories.

The FSIS auditors visited the LFDA government testing laboratories in Campinas and Pedro Leopoldo. These laboratories are accredited by INMETRO to ISO/IEC 17025 standards, and perform microbiological testing of governmental samples, including RTE product samples. The methods that the Campinas and Pedro Leopoldo LFDA use for *Salmonella* and *Lm* testing are included in the laboratories' scopes of accreditation. The FSIS auditors noted that the laboratories use the FSIS MLG methods for the detection of *Salmonella* (MLG 4C.08) and *Lm* (MLG 8.11) on identical test portions used by FSIS, i.e., 325 g for *Salmonella* and 25 g for *Lm*. For STEC testing, the FSIS auditors noted that both laboratories employed the FSIS MLG methods for the detection of *E. coli* O157:H7 (MLG 5A.04 and MLG 5.09) and non-O157 STEC [i.e., O26, O45, O103, O111, O121, and O145] (MLG 5B.05). Although these laboratories were unable to obtain STEC control strains that satisfy INMETRO requirements for accreditation, the FSIS auditors noted that both laboratories are including appropriate replacement STEC controls during analyses.

During the on-site audits of these facilities, the FSIS auditors verified the sample receiving areas and sample receipt, acceptance criteria (including temperature requirements), handling, storage, and traceability, and reviewed the reporting criteria. Both facilities utilize a local Laboratory Information Management System (LIMS) to ensure traceability and proper results reporting to the CCA. The FSIS auditors verified equipment was routinely calibrated and maintained, and that reagents were properly labeled and maintained (e.g., expiration dates for prepared media). The FSIS auditors noted that analysts undergo "three phase" training in laboratory methods with proper supervisory review, and reviewed associated proficiency testing records. No concerns were identified.

The FSIS auditors visited four establishments preparing TPCS products. Brazil's legislation defines commercial sterilization as the sterilization achieved by means of moist heat with an F_0 value greater than or equal to three minutes or to a 12-$\log_{10}$ reduction in *Clostridium botulinum*, followed by immediate chilling, as defined by item c) of Article 172 of *Decree No. 9,013/2017*. In addition to process times, process temperatures, and critical factors, *Circular Letter No. 28/1978* requires establishments to monitor initial temperatures, venting, vacuum and head space, and control instruments (e.g., temperature recorders, indicator thermometers). *Circular Letter No. 28/1978* also requires establishments producing TPCS to provide the SIF with detailed descriptions (e.g., process schedules) for each type of product for government review and

approval and identifies specific critical factors that must be identified by the production description.

Specific on-site verification activities conducted by the FSIS auditors included the review of process schedules for products exported to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat-distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians. The FSIS auditors identified deficiencies related to the verification of retort operations and maintenance at three of the four audited establishments, none of which were considered an immediate threat to food safety. This included incidental higher temperature readings from the time/temperature recording device than the indicating temperature device (both readings were higher than the critical limit) at two facilities; placement of bleeders (used to provide circulation of steam in the retort) in a manner where official personnel could not verify operation at one facility; and operation of retorts at partial capacity without validation of the process (which can affect the venting schedule) at one facility.

During interviews held with local inspection personnel at two of the audited facilities, the FSIS auditors were informed that routine verification activities for retort operations included only records review and did not include a hands-on (in situ) verification component. This is inconsistent with the CCA's *Circular Letter No. 34/2016*, which requires official inspection plans to include a hands-on (in situ) verification component. DIPOA needs to take the necessary corrective actions to ensure the standardization of inspection practices throughout all establishments certified to export TPCS product to the United States.

- The FSIS auditors identified deficiencies related to the verification of operation and maintenance of retorts at three of the four establishments preparing TPCS products, including deficiencies related to retort temperature recording at two establishments. The FSIS auditors also noted that official verification activities at two of these facilities only included an element of records review and did not include a hands-on or direct observation component.

The inspection officials took immediate action upon notification of these findings. Additionally, the auditors directly observed the establishments' processes and reviewed establishment records and supporting documents to ensure that the identified deficiencies did not constitute an imminent threat to public health.

The FSIS auditors found that Brazil's meat inspection system has a microbiological testing program organized and administered by the national government, and that DIPOA has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While Brazil's program includes microbiological sampling requirements that are equivalent to United States standards, the FSIS auditors identified deficiencies related to microbiological testing practices that could potentially impact the accuracy of results, as well as deficiencies related to the verification of retort maintenance and operation.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 28, 2019, in Brasília, Distrito Federal, Brazil, with DIPOA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The FSIS auditors identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS

- The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection at three of the seven audited beef slaughter and processing establishments.
- The CCA does not maintain written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection.
- The FSIS auditors identified deficiencies at five of the seven audited beef slaughter and processing establishments related to the control of SRM. These included the potential for contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, inadequate trimming of lingual tonsils, and failure to document the removal of dorsal root ganglia and vertebral column at deboning.
- The FSIS auditors identified concerns in meeting the APHIS requirements outlined in 9 CFR 94.29 regarding carcass maturation. This included the use of a set of inaccurate pH meters at one establishment, as well as the inability for all audited establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i).

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The two audited government laboratories are not analyzing the entire N-60 sample if the sample submission is greater than the size of the test portion prescribed by the screening method (325 g ±10 %).
- The FSIS auditors identified deficiencies related to the verification of operation and maintenance of retorts at three of the four establishments preparing thermally processed, commercially sterile products, including deficiencies related to retort temperature recording at two establishments. The FSIS auditors also noted that official verification activities at two of these facilities only included a records review and did not include a hands-on or direct observation component.
- The regional Inspection SIPOA offices do not have direct access to all official microbiological testing results provided by testing laboratories.
- At the single audited swine slaughter and processing establishment, the establishment personnel were using the m/M criteria to analyze the generic *E. coli* results from samples collected using the carcass sponge technique. However, the use of the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method.

Prior to the audit's conclusion, the CCA demonstrated that it had instituted proper inspection procedures for post-mortem inspection and committed to address the remainder of the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation

of proposed corrective actions and base future equivalence verification activities on the information provided.

Furthermore, the potential contamination of head or cheek meat with brain tissue constitutes a significant audit finding for which FSIS requested immediate assurances from the CCA to demonstrate that establishments have taken the necessary measures to prevent the use of contaminated head or cheek in exported product. In the absence of such assurances, FSIS will consider delisting of these establishments as a necessary measure to prevent the use of suspect beef source materials in the manufacture of products intended for export to the United States. FSIS has communicated the animal health findings related to the control of FMD to APHIS, which has committed to following-up on these issues.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

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 Alimentos S/A Hulha Negra Rio Grande do Sul	06/12/2019	SIF226	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
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. Periodic Supervisory Reviews	
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. Thermally Processed Commercially Sterile Products	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/12/2019

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 São Paulo	06/17/2019	SIF337	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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. Thermally Processed Commercially Sterile Product	X
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

38. Stagnant water was observed pooling in shallowed ground next to the raw meat product receiving area due to a leaking pipe. The condition has caused flies and insects breeding and is posing pest entry into the establishment. The auditors further observed the trash and debris collected under the loading dock vestibule, which may cause insanitary conditions and product adulteration.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

57. Interviews with inspection personnel indicated that routine verification activities included only records review, and did not include a “hands-on” verification component. Discussions with DIPOA representatives confirmed that this does not meet the requirements of Memorandum-Circular n° 34/2016, as it is the CCA’s expectation that the inspection plans referenced therein include a “hands-on” verification component.

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 Andradina São Paulo	06/18/2019	SIF385	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

67. The production record showed that the readings from the time/temperature recording device were higher than those from the indicating temperature device. The auditors noted the following discrepancies at two instances:

1. Temperature Indicating Device 122 C Time/temperature recording device 122.8 C
2. Temperature Indicating Device 121 C Time/temperature recording device 122.7 C

Since both readings were higher than the critical limit of the CCP, the product was not affected. However, this discrepancy showed that the chart record does not meet the requirement in MAPA Circular Nº 28 of June 19, 1978, which states “Each autoclave must have a temperature recorder adjusted to exactly record the temperature shown by the mercury thermometer. The inspector must observe if the control instruments comply with these requirements.”

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil’s inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/18/2019

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 S/A Barretos, São Paulo	06/14/2019	SIF 421	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

57 (1). The record of the readings from the time/temperature recording device was higher than that from the indicating temperature device. This does not meet the requirement of 9 CFR 431.6 (a)(2). which states, “the temperature recording chart should be adjusted to agree with, but must never be higher than, the known accurate indicating temperature device.”

57 (2). Three of the eight bleeders on each retort observed were located in a manner that interfere with the inspection verification activity. This does not meet the FSIS regulation 9 CFR 431.6(b)(iv), which requires all the bleeders be wide open and must be arranged so that the retort operator can observe that they are functioning properly.

57 (3). Interviews with inspection personnel indicated that routine verification activities included only records review, and did not include a “hands-on” verification component. Discussions with DIPOA representatives confirmed that this does not meet the requirements of Memorandum-Circular n° 34/2016, as it is the CCA’s expectation that the inspection plans referenced therein include a “hands-on” verification component.

57 (4). The auditor found in the production records that some of the retort cycles were not full (135 cans instead of 180). The current venting schedule on file may not support the thermal process of a partial load cycle. Inadequate venting may cause cold spot in the chamber and result in lower than designed lethality for some of the product in the cycle.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/14/2019

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 S/A Rod. Go 050, Km 41 S/N Zona Rural Palmeiras de Goias, Goiás	06/26/2019	SIF431	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

40. The FSIS auditors observed the lighting in the maturation chillers and noted that the lighting under the compressors appeared inadequate. An establishment employee measured the lighting using a light meter, and at the top of the hindquarter of the carcass, the lighting meter measured 198 lux. However, at the fore-quarter area of the carcass, the lighter meter measured 4 lux. The company's self-control program requires that the lighting in the maturation chillers be at least 110 lux.

41. The FSIS auditors observed the freezer for products under official veterinary control contained a build-up of ice and frozen condensate, resulting in insanitary conditions. However, the auditors did not observe exposed products being stored in the freezer at the time of the observation.

46. While observing slaughter operations, the FSIS auditors observed that the sanitizer was not working at the dehorning step. The establishment's self-control program requires that equipment and utensils used on the carcass be sanitized in between animals using water at temperatures greater than 82.5 degrees Celsius.

57. The establishment did not institute measures to prevent leakage of brain tissue from the knock-hole of cattle during head washing. All cattle slaughtered in the facility were handled as though they were thirty months of age or older within the context of the establishment's written control program for specified risk materials (SRM). Therefore, brain tissue from all slaughtered animals is to be considered SRM. However, no direct contamination by brain tissue was observed by the FSIS auditors during the head washing and head/cheek meat harvesting processes.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil's inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

55. While observing slaughter operations and SIF post-mortem inspection procedures, the FSIS auditors observed the SIF inspector fail to palpate the kidneys during post-mortem inspection, which does not comply with Brazil's procedures for beef slaughter inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/26/2019

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 Ituiutaba Minas Gerais	06/14/2019	SIF 504	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliance was not identified by Brazil's inspection officials during the establishment review:

52. The floors and walkways of the ante-mortem holding area were not maintained in a manner to provide good footing for livestock. The FSIS auditors noted several areas where the concrete had degraded, resulting in holes, cracks, or other obstacles which could impact the ambulation of livestock as they proceed to slaughter.

57. The establishment did not institute measures to prevent leakage of brain tissue from the knock-hole of cattle during head washing. All cattle slaughtered in the facility were handled as though they were thirty months of age or older within the context of the establishment's written control program for specified risk materials (SRM). Therefore, brain tissue from all slaughtered animals is to be considered SRM. However, no direct contamination by brain tissue was observed by the FSIS auditors during the head washing and head/cheek meat harvesting processes.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil's inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/14/2019

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 Campo Grande Mato Grosso do Sul	06/21/2019	SIF1662	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

15. The establishment's HACCP flow chart for deboning operations did not specifically identify the point at which removal of the vertebral column occurs.

57. The establishment did not institute measures to prevent leakage of brain tissue from the knock-hole of cattle during head washing. All cattle slaughtered in the facility were handled as though they were thirty months of age or older within the context of the establishment's written control program for specified risk materials (SRM). Therefore, brain tissue from all slaughtered animals is to be considered SRM. However, no direct contamination by brain tissue was observed by the FSIS auditors during the head washing and head/cheek meat harvesting processes.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil's inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

55. The head tattoos used to maintain synchronization between heads, viscera, and carcasses during post-mortem inspection were illegible. As a result, inspection personnel could not effectively identify which head corresponded to which viscera and carcass when asked by the FSIS auditors during the establishment tour. Synchronization between heads, viscera, and carcasses is important in ensuring that accurate assessment to the health status the animal during post-mortem inspection, especially when carcasses (and associated viscera and heads) are presented for additional veterinary review.

55. The FSIS auditors noted that eyes were being harvested by the establishment from bovine skulls prior to completion of official post-mortem inspection of the head. The eyes were being removed by an establishment employee just after the official inspection of lymph nodes, and prior to official inspection of the masticatory muscles (these procedures were conducted by two separate official inspectors). Consequently, the eyes would not be routinely available should the carcasses be railed-out for additional veterinary review and could impact the ability to make accurate dispositions regarding "cancer eye" (ocular squamous cell carcinoma), icterus (jaundice), or other generalized conditions. Discussions with representatives from DIPOA (Brazil's central competent authority) indicated that this practice did not meet Brazil's meat inspection requirements, and it is expected that eyes not be removed until post-mortem inspection is completed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/21/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Marfrig Alimentos S/A . Promissao São Paulo	06/19/2019	SIF2543	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

52. In the outdoor walkway leading to the stunning area, a restraining door had a broken steel pipe with sharp edges could cause injury to animal. The bottom edge of the same door was also had sharp protruding edges. A portion of the walkway was not maintained in a manner to provide good footing for livestock, presenting several areas where the walkway cleats (ridges) were either degraded or missing.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil’s inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/19/2019

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 Catarinense Rua Aury Luiz Bodanese 401 E Barrio Eufapi Chapeco Santa Catarina	06/21/2019	SIF3548	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

29. The establishment was using m/M criteria to analyze the generic *E. coli* results from samples collected using the carcass sponge technique. However, the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method. Establishments employing swabbing to sample carcasses are to employ statistical process control (SPC) techniques for the interpretation of test results. This derived from a discrepancy in the Brazilian requirements for the evaluation of generic *E. coli* sponging results in swine carcasses specifically. *Circular Letter No. 273/97/DIPOA* indicates that results for generic *E. coli* testing are evaluated using statistical process control, but *Circular Letter No. 682/2012/CGPE/DIPOA* includes alternative criteria for swine. These alternative criteria are similar to those values outlined in 9 CFR 310.25 and used by FSIS domestically for the interpretation of testing results collected through the excision (not sponging) method. Brazil has not received an equivalence determination to permit the use of excision criteria for the evaluation of swine carcass testing results using the excision method.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

36. Interviews with inspection officials indicated that they were not familiar with the contents of *SDA/MAPA no. 132/2012* and *Normative Instruction 42/1999*, which direct field personnel to target animals suspected of being treated with veterinary residues at ante-mortem.

54. There is no specific standard within Brazil’s inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/21/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Marfrig Alimentos S.A. . Rod. BR 267 Km 35 Distrito Industrial Bataguassu São Paulo	06/18/2019	SIF 4238	Brazil
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

15. The establishment's HACCP flow chart did not identify the use of the steam-vac which was occurring at three specific points in the slaughter process.

57. During the on-site review of the slaughter process, the FSIS auditors observed identified an instance where the procedure for the removal of lingual tonsils was not implemented in accordance with the establishment's written program. The establishment's program requires trimming of the lingual tonsil to occur just behind (posterior) the last pair of vallate papillae found at the base of the tongue. However, the FSIS auditors noted that, in this instance, actual trimming had begun approximately half an inch further back than this point. This resulted in half an inch of tonsillar tissue remaining on the major portion of the tongue. The FSIS auditors confirmed with inspection personnel that only those tongues for which the establishment could demonstrate effective process control for removal of tonsillar tissue would be certified for export to the United States. This included tongues from the current production day, as well as those stored either locally, or at a sister facility (SIF 2543).

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. There is no specific standard within Brazil's inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

55. The head and viscera tattoos used to maintain synchronization between heads, viscera, and carcasses during post-mortem inspection were illegible. Consequently, inspection personnel could not effectively identify which head corresponded to which viscera and carcass when asked by the FSIS auditors during the establishment tour. Synchronization between heads, viscera, and carcasses is important in ensuring that accurate assessment to the health status the animal during post-mortem inspection, especially when carcasses (and associated viscera and heads) are presented for additional veterinary review.

55. A half-carcass which was contaminated with bile on its internal surface (approximately 10 square inches, midway up the carcass) was observed passing the post-mortem inspection station without any additional action taken by the official inspector to remove the contamination. The FSIS auditors pointed out this deficiency to the supervisory veterinarian who was leading the establishment tour, who immediately instructed an establishment employee to trim the contaminated area to the satisfaction of the inspector.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/18/2019

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 Margem Direita, Zona Rural Campo Grande Mato Grosso do Sul	06/24/2019	SIF 4400	Brazil
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Brazil's inspection officials during the establishment review:

57. The establishment did not institute measures to prevent leakage of brain tissue from the knock-hole of cattle during head washing. All cattle slaughtered in the facility were handled as though they were thirty months of age or older within the context of the establishment's written control program for specified risk materials (SRM). Therefore, brain tissue from all slaughtered animals is to be considered SRM. However, no direct contamination by brain tissue was observed by the FSIS auditors during the head washing and head/cheek meat harvesting processes.

In addition, FSIS identified the following findings related to the implementation of Brazil's inspection system:

54. Interviews held with the SIF veterinarian responsible for conducting ante-mortem inspection indicated that he did not always observe animals in motion. The SIF veterinarian explained that he visually observed the animals in the pens for any abnormalities. He explained that if there are concerns regarding the animal's demeanor or posture, he would request an establishment employee to force the animal to move for additional observation.

54. There is no specific standard within Brazil's inspection system which stipulates the body temperature at which livestock should be condemned during ante-mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	06/24/2019

Appendix B: Foreign Country Response to the Draft Final Audit Report

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
GENERAL COORDINATION FOR CONTROL AND EVALUATION - CGCOA
Esplanada dos Ministérios, Bloco D, Anexo Ala A, 4º Andar, Sala 420/422 - Bairro Zona Cívico-Administrativa - DF, CEP 70043-900
Tel: (61) 3218-2719 - http://www.agricultura.gov.br

INFORMATION 48/CGCOA/DIPOA/SDA/MAPA
CASE FILE Nº 21000.013116/2019-05

TO: EDILENE CAMBRAIA SOARES, LEIDINAR ALVES DA SILVA, NUBIA CRISTINA SANTOS RIBEIRO

Subject: **USA: Letter 91/2019 FSIS/USDA. Additional Clarification About Specific Risk Material - SRM.**

This communication addresses Letter 91/2019 FSIS/USDA (SEI nº 8411657) which requests that DIPOA provide additional data about the control of Specific Risk Material (SRM) in beef as a result of the findings observed during the FSIS audit carried out on June 10-28, 2019, and also highlighted in the audit exit meeting on June 28, 2019.

It is reported that, during the June audit, the FSIS auditors observed that 4 out of 7 beef slaughterhouses did not have measures to prevent brain leakage through the stunning hole opened by the penetrating captive-bolt gun.

They also mentioned that the establishments did not have measures to prevent the contamination of edible products with brain tissue during head washing and harvesting of head and cheek meat; they showed concern about the contamination of meat-based products with SRM.

As a response to the FSIS/USDA audit findings, DIPOA determined, through Circular Letter (Ofício-Circular) 62/2019/DIPOA/SDA/MAPA de 27/06/2019 7716197, that it is prohibited to use head meat as raw material to produce heat-processed products, of any nature, to be exported to the United States of America. This was also a result of the statements by the FSIS auditors in the exit meeting on June 28, 2019, which questioned the use of head meat (including cheek meat) as raw material for the preparation of products to be exported to the United States of America, and that the use of this type of raw material must have an additional control beyond those controls that are already in place by the Brazilian plants during the slaughter step (such as the use of a plug for the stunning hole to prevent brain leakage).

In Letter (Ofício) 144/2019/DIPOA/SDA/MAPA – MAPA (SEI nº 7802359), DIPOA requested a notification to be sent to the establishments eligible to export heat-processed beef products to the US so that they can provide data about the use of head meat (including cheek meat) as raw material for the preparation of heat-processed products to be exported to the United States of America in the period since the last FSIS/USDA (2017) audit by June 28, 2019, including the records that prove their use.

Furthermore, considering the establishments' answers in which they declare that they **do not** use this type or raw material, and also *Title 9 Part 319 → Subpart D → §319.100 of the Electronic Code of Federal Regulations e-CFR that, among others, mentions "Beef cheek meat, beef head meat*

and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of this product when trimmed as specified in §319.81. When beef cheek meat, beef head meat, or beef heart meat is used in preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter", information was requested regarding approved registrations of "Corned beef" containing head meat (including cheek meat) and their percentage on the list of ingredients. Additional clarification may be requested regarding the origin, control and traceability.

According to CFR 319.100, beef cheek meat, beef head meat and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of Corned Beef when trimmed as specified in §319.81. When beef cheek meat, beef head meat and beef heart meat are used in preparation of this product, its presence must be reflected in the declaration of ingredients as specified in Part 317 of this subchapter.

The establishments eligible to export heat-processed beef products to the USA: SIF 1690, SIF 421, SIF 337, SIF 385, SIF 260, SIF 2543, SIF 226.

After having analyzed the answers of the involved establishments registered with the Federal Inspection Service (SIF) and the respective SIPOAS, we inform you about the following:

1. SIF 1690 Meat Snack Partners do Brasil LTDA:

a) the company declares that it does not use head meat (including cheek meat);

b) the company produced records on the receiving of raw material eligible to be exported to the United States, demonstrating that it only receives beef cuts (outside, topside and eye of round);

c) the company declares that it does not have product containing head meat (including cheek meat) as raw material and listed all of its labels approved by DIPOA

2. SIF 226 Pampeano Alimentos S/A:

a) the company declares that it does not use head meat (including cheek meat) in the products to be exported to the United States;

b) the company presented the traceability of the products exported to the United States in 2017, 2018 and until July 2019

c) the company states that it has control of traceability and eligibility of raw material that could contain head meat (including cheek meat), guaranteeing that these products have not been used in products to be exported to the US;

d) the company states that there are no labels approved for corned beef whose list of ingredients has head meat (including cheek meat)

3. SIF 421 Minerva S/A

a) the company produced documentation that states that it does not use head meat (including cheek meat) as raw material for the production of heat-treated products to be exported to the US. The documents are in Appendix 7843537 **and in the local Inspection Service dispatch (7843734);**

b) the company clarifies that it does not have approved labels for cooked canned beef containing head meat (including cheek meat) in its list of ingredients

4. SIF 385 JBS S/A

a) the company stated that it has chosen not to use head meat (including cheek meat) as raw material for corned beef because it is mandatory to identify that on the label in accordance with CFR 319.100;]

b) the company states that it controls the use of raw material by means of specific codes per market and that none of the codes for these raw materials is used in the production of heat-treated products to be exported to the US;

c) the company states that there is no registration of approved labels of corned beef whose list of ingredients has head meat (including cheek meat). There are no approved labels for corned beef containing “industrial meat” in its list of ingredients.

5. SIF 260 MEAT SNACK PARTNERS DO BRASIL LTDA

a) the company states that it does not use head meat to produce heat-processed meat to the US. It produced a summary of production of the raw materials used per date of production and other documents that underpin the control of receiving of raw material.

b) the company produces only Beef jerky and is not eligible to produce corned beef.

6. SIF 2543 MARFRIG GLOBAL FOODS S/A

a) the company informed us that it does not use head meat to produce heat-processed meat to the US; in the case of frozen cooked beef

b) The technical specifications define the raw material to produce frozen cooked beef to the US as cuts of chuck, shoulder, brisket, chuck tender, blade clod, ribs, silverside and topside.

c) the company produces only frozen cooked beef to the US and is not eligible to produce corned beef.

7. SIF 337 JBS S/A

a) regarding not using head meat to produce heat-processed meat to the US.

b) the company states that it controls the use of raw material by means of specific codes per market and that none of the codes for these raw materials is used in the production of corned beef or products that undergo commercial sterilization for the US;

c) the company reported that it has only performed one test with “cheek beef” as raw material, which was used to produce frozen cooked beef to the US (cooked beef cheek meat) which was exported under CSI (International Health Certificate) number 086.379/19; which is stored in a warehoused in Pedricktown NJ.

d) CSI (International Health Certificate): 086379/19 | Category: Fully Cooked | Product: FROZEN COOKED MEAT | Code: 377774 - COOKED BEEF CHEEK MEAT USA | Date of production February 26, 2019 | Total volume: 1097.712 Kg.

e) The product was exported the day before the publication of the Circular Letter (Ofício-Circular) 62/2019/DIPOA/SDA/MAPA of June 27, 2019 7716197 (which prohibits head meat (including cheek meat) as raw material for heat-processed products) and was underpinned based on the standing by the Agricultural Attaché who consulted APHIS/USDA, which stated that head and cheek meat are permitted when accompanied by a meat inspection certificate and processed according to CFR 94.4 (b) from an approved establishment for cooked meat and accompanied by an indicator piece 2266270.

f) the company informed us that **there are no** approved labels for corned beef whose list of ingredients has head meat (including cheek meat). There are no approved labels for corned beef containing “industrial meat” in its list of ingredients.

Conclusion:

After checking with all establishments eligible to export heat-treated beef products to the US from the period since the last FSIS/USDA (2017) audit until June 28, 2019, we have verified that:

g) All establishments informed us that they **have not used head meat (including cheek meat) in heat-processed products to be exported to the United States of America**; except for SIF 337, which reported that it has performed one production test using cheek beef as raw material, which is segregated in a warehouse in the US;

h) All the establishments that manufacture products that undergo commercial sterilization (corned beef) to be exported to the United States of America informed us that **they do not have registration for products (labels) whose list of ingredients include head meat (including cheek meat);**

Thus, regarding FSIS/USDA’s concern in Letter 91/2019 regarding the possibility of contamination of meat products with Specific Risk Materials (SRM) during head washing and harvesting of head and cheek meat, based upon a belief that the establishments did not have measures to prevent the contamination of edible products with brain tissue, we can conclude that there have been no exports to the United States of America of meat products **whose list of ingredients included head meat (including cheek meat), proving that there has been no risk of the heat-processed products exported to the United States being contaminated with brain matter that may have contaminated head meat due to failure in the slaughter operating procedures.**

We conclude that the measures that have been adopted to prohibit the use of head meat (including cheek meat) as raw material for heat-processed products <u>are the most effective measures for guaranteeing the safety of the products in the event of a possible contamination of the head meat</u>. The answer to these questions does not exempt the establishments from the responsibility of taking effective supplementary measures to guarantee the prevention of contamination during slaughter.

Regarding the guarantees of the requirement that the certified establishments produce materials of origin in compliance with Circular Letter (Ofício Circular) 62/2019/DIPOA/SDA/MAPA (7716197), published on June 27, 2019, we inform you that it has been made mandatory for official verification of the formulation of heat-treated products (commercial sterilization) regarding the prohibition of using head meat and cheek meat as heat-processed raw material in commercially sterile products to be exported to the USA, as well as the definition of the frequency and guidance for measures to be taken in the event of non-compliances being found, in order to prevent non-compliant products from being exported to the US as per Circular Letter (Ofício Circular) 26/2019/CGCOA/DIPOA/SDA/MAPA (SEI nº 8426434).

Yours,

Document electronically signed by **JULIANA SATIE BECKER DE CARVALHO CHINO**, **General Coordinator for Control and Evaluation**, on 19/09/2019, at 11:39, official Brasilia time, Based on Article 6, Paragraph 1, of Decree 8,539, of October 8, 2015.

This document bears the electronic signature of **ANA LUCIA DE PAULA VIANA**, **Director of the Department of Inspection of Animal Products**, on 9/19/2019, 11:41 AM, official Brasilia time, based on article 6, paragraph 1, of Decree no. 8,539, enacted October 8, 2015.

You may check that this document is authentic at http://sistemas.agricultura.gov.br/sei/controlador_externo.php?acao=documento_conferir&id_orgao_acesso_externo=0, giving verification code **8428162** and CRC code **1C4378D7**.

Reference: Case File 21000.013116/2019-05 SEI 8428162

APPENDIX A

Responses and additional comments from the Brazilian competent authority regarding the audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from June 10 through 28, 2019

N°	***FSIS findings***	***Corrective actions proposed by the CCA and additional comments***
COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)		
01	*The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection at three of the seven audited beef slaughter and processing establishments.*	These were sporadic flaws that also characterize a failure to comply with current Brazilian legislation in force. During the on-site verification audit all the findings were transmitted to the Federal Inspection teams in the Establishments for the appropriate corrections; some findings were addressed and adjusted immediately. After *Appendix A: Individual Foreign Establishment Audit Checklist* was received, the individual reports were forwarded to the audited establishments and SIPOAs for additional measures to be taken. The actions were assessed and deemed satisfactory by the SIPOA and DIPOA. The findings will also be included in guidance for auditors of the Division for Audits in Establishments (DAE) so as to maintain continuous verification, both in the establishments at which the findings were observed, and in others. Furthermore, we state that the Federal Agricultural Inspectors/Auditors (AFFAs) in the audited units have been trained in regard to the findings contained in the report and its appendices, in a face-to-face setting, during the training entitled Standardization of Ante-mortem and Post-mortem Oversight and Inspection Procedures for Slaughter Animals ("*Padronização de procedimentos de fiscalização e inspeção ante e post mortem de animais de abate*") which was held at ENAGRO - Brasília/DF, as given in SEI Case File No. 21000.013547/2019-63. The certificates and course contents of the training initiative are attached to this document as Appendix 1.

02	*The Central Competent Authority (CCA) does not maintain written guidelines that prescribe the body temperature at which livestock (i.e., beef cattle and swine) are to be condemned during ante-mortem inspection*	A consolidated protocol containing all the specific requirements for the US market has been prepared. In this document (CIRCULAR OFFICIAL LETTER Nº 112/2019/DIPOA/SDA/MAPA – Appendix 2) we defined the reference temperatures for the thermometry of animals for slaughter, during examinations that are supplementary to the Ante-mortem inspection activities, so as to meet the specific requirement of 9 CFR 309.3. In items 6.1.1.3 and 7.1.2, the document stipulates that if pigs or bovines are detected during ante-mortem inspection showing temperatures equal to or above 41ºC in the case of pigs, and 40.5ºC in the case of bovines, these animals must be condemned.
03	*The FSIS auditors identified deficiencies at five of the seven audited beef slaughter and processing establishments related to the control of specified risk material (SRM). These included the potential for contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, inadequate trimming of lingual tonsils, and failure to document the removal of dorsal root ganglia and vertebral column at deboning*	Reports of the FSIS auditors state that cross- (or direct) contamination was not observed during the washing process for heads, and subsequent processes for obtaining raw materials from them (head and cheek meat). However, based upon the audit findings, DIPOA determined in timely fashion, by publishing Official Circular Letter no. 62/2019/DIPOA/SDA/MAPA dated 27/06/2019 7716197, to ban the use of head meat as raw material for heat-processed production of any nature intended for export to the United States. Furthermore, in response to the emphasis given by the FSIS auditors during the Exit Meeting held on 28/06/2019, where the possible use of head meat (including cheek meat) as raw material for making products for export to the United States of America was questioned, a letter dated 20/09/19 was sent to FSIS, the explanations contained in which were considered to be sufficient, and may be the subject of verification in a future audit. We stress that all the measures were defined and fully implemented after the document was published, and are verified on a daily basis during the oversight exercised by the Federal Inspection Service in the Establishments, and during DAE audits on establishments approved for export to the USA. Additionally, the ban is part of the protocol of compliance with US requirements (Appendix 2 - items 6.1.1.7; 6.2.1.1 and 8). Regarding the removal of the lingual tonsils and the spinal column, as cited in the body of the certificate *"(...) Furthermore, the FSIS auditors identified deficiencies related to the removal of lingual tonsils (one establishment) and* *documentation of removal of dorsal root ganglia and vertebral column (one*

		establishment). " We acknowledge these findings, which were sporadic flaws showing a failure to comply with the legislation in force. Many corrective actions were adopted during the on-site audit, while after *Appendix A: Individual Foreign Establishment Audit Checklist* was received, it was forwarded to the SIFs and SIPOAs for additional measures to be taken. The actions were assessed and deemed satisfactory by the SIPOA and DIPOA. The findings will also be included in guidance for auditors of the Division for Audits in Establishments (DAE) so as to maintain continuous verification, both in the establishments at which the findings were observed, and in others. Furthermore, we state that the Federal Agricultural Inspectors/Auditors (AFFAs) in the audited units have been trained in regard to the findings contained in the report and its appendices, in a face-to-face setting, during the training entitled Standardization of Ante-mortem and Post-mortem Oversight and Inspection Procedures for Slaughter Animals ("*Padronização de procedimentos de fiscalização e inspeção ante e post mortem de animais de abate*") which was held at ENAGRO - Brasília/DF, as given in SEI Case File No. 21000.013547/2019-63. The certificates and course contents of this training initiative can be found as an attachment to this document (Appendix 1).
04	*The FSIS auditors identified concerns in meeting the APHIS requirements outlined in 9 CFR 94.29 regarding carcass maturation. This included the use of a set of inaccurate pH meters at one establishment, as well as the inability for all audited establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i).*	Regarding the calibration of the pH meters, the findings were based on the note: *(...). The first concern relates to observation of the use of a set of inaccurate pH meters at one establishment, as the auditors observed that the pH meters did not measure the accurate pH of the calibration solutions after being calibrated*." A Protocol of Compliance with US Sanitary Requirements has been drafted (Appendix 2) and in item 6.3.1 this gives the routine cleaning of the equipment's bulb, and calibration of the device in accordance with manufacturer's specifications, as an obligation of the establishments. It also lays down that the Official Service must include the evaluation of these devices in its inspection plan so that they will be officially verified at the frequency determined by Internal Standard (*Norma Interna*) 01/2017. Regarding the point quoted in the body of the report: "(...)*The second concern derived from discussions held with the government officials and inspection personnel, reflects a country-wide practice, where it was indicated that carcasses enter the maturation chamber on Friday, the pH would not be measured until Monday. This practice does not permit the establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation* *chamber as required by 9 CFR 94.29(i). FSIS has communicated these findings to APHIS,*

		who has committed to following up on these issues. At this time, there are no establishments in Brazil eligible to export raw beef to the United States." It is our understanding that what is set forth in 9 CFR 94.29(i) is clear when it cites the need to reach a pH less than 6.0 after 48h: "*Any carcass in which the pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0* ***after 48 hours****, the meat from the carcass may not be exported to the United States."* [emphasis added] We believe that the procedure in force does not pose risks of being a vehicle for the foot-and-mouth disease virus; nonetheless, we deem this issue to be a certification requirement and have included in the Protocol of Requirements a specific and clearer mention of the measurement of the pH in carcasses after 48 hours of maturation, as set down in the preliminary report (item 6.3.1 c of the protocol): *"Those carcasses that did not reach pH less than 6.0 may be additionally maturated for another 24 hours, after which the pH must be taken again. After this second pH measurement, if the pH is not less than 6.0, the carcass cannot be exported to the US as fresh beef."*
COMPONENT SIX: **GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**		

05	*The two audited government laboratories are not analyzing the entire N- 60 sample if the sample submission is greater than the size of the test portion prescribed by the screening method (325 g ±10 %)*	The body of the report states that "(...) However, the FSIS auditors noted that samples collected were typically far greater than the anticipated 325 grams and observed the collection of a government sample weighing 830 grams at one establishment. At both the Campinas and Pedro Leopoldo facilities the FSIS auditors noted that during the on- site audit that laboratory personnel may not be analyzing the entire N-60 beef trim sample as received from establishments. Laboratory personnel at both facilities reported routinely weighing and analyzing a 325-gram test portion, even if the weighed test portion did not include all 60 pieces of trim from the N-60 sample." The document entitled CIRCULAR OFFICIAL LETTER NO. 10/2019/CGAL/DTEC/SDA/MAPA (Appendix 3) ratifies the information given to the FSIS auditors in the Exit Meeting. The document informs the LFDAs (Federal Animal and Plant Health Laboratories) that: " *(...) on those occasions when they receive samples weighing over 325g+10%, such samples must be split into 2 aliquots and analyzed as two samples, such that all 60 pieces of meat that have been sent be representative of the sample sent to the laboratory. We hereby request that this adjustment be incorporated into the Standardized Operating Procedures of the respective LFDA laboratories*" As a supplement to this, DIPOA published Official Letter No. 40/2019/CRISC/CGPE/DIPOA/SDA/MAPA (Appendix 4) which contains guidance to be followed by all those individuals involved in sampling for STEC testing in bovine slaughterhouses. It was emphasized that sampling for STEC assays by Method N60 must have the suitable weight of the sample (325g +/- 10%). This document also states that the Manual of Sample-Taking for Animal Products has been revised, and guidance has been included for sample-taking to meet Normative Instruction no. 60/2018. The Manual is available on the DIPOA web page, in the Publications Area, at http://www.agricultura.gov.br/assuntos/inspecao/produtosanimal/publicacoes-dipoa.

06	*The FSIS auditors identified deficiencies related to the verification of operation and maintenance of retorts at three of the four establishments preparing thermally processed, commercially sterile products, including deficiencies related to retort temperature recording at two establishments. The FSIS auditors also noted that official verification activities at two of these facilities only included a records review and did not include a hands-on or direct observation component*	The finding was based on the following observations: (...). *The FSIS auditors identified deficiencies related to the verification of retort operations and maintenance at three of the four audited establishments, none of which were considered an immediate threat to food safety. This included incidental higher temperature readings from the time/temperature recording device than the indicating temperature device (both readings were higher than the critical limit) at two facilities; placement of bleeders (used to provide circulation of steam in the retort) in a manner where official personnel could not verify operation at one facility; and operation of retorts at partial capacity without validation of the process (which can affect the venting schedule) at one facility. During interviews held with local inspection personnel at two of the audited facilities, the FSIS auditors were informed that routine verification activities for retort operations included only records review and did not include a hands-on (in situ) verification component. This is inconsistent with the CCA's Circular Letter No. 34/2016, which requires official inspection plans to include a hands-on (in situ) verification component. DIPOA needs to take the necessary corrective actions to ensure the standardization of inspection practices throughout all establishments certified to export TPCS product to the United States.*" "*The FSIS auditors found that Brazil's meat inspection system has a microbiological testing program organized and administered by the national government, and that DIPOA has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While Brazil's program includes microbiological sampling requirements that are equivalent to United States standards, the FSIS auditors identified deficiencies related to microbiological testing practices that could potentially impact the accuracy of results, as well as deficiencies related to the verification of retort maintenance and operation*." To correct this deficiency, the Protocol of Compliance with US sanitary Requirements (Appendix 2), has been prepared, and in item 6.2.1.3, cites the following obligations applying to establishments, which must be met immediately:

		During processing of the products, two measuring instruments must necessarily be used for production monitoring: one static temperature indicator, fixed to the equipment, plus one device able to record time/temperature continuously during the entire process (thermo-recorder). The difference between the two measuring systems may not be greater than 0.5°C, and the thermo-recorder must be adjusted in such a way that the temperature recorded will not be, at any moment of the process, greater than that observed for the static temperature-measuring equipment. *Regarding the number of items of packaging that were present in the retorts during the thermal processing cycles, the sterilization machines must work under the same conditions that are used during penetration and heat distribution tests - in other words, the equipment must be at its maximum capacity. In this way, if production is insufficient to fill a machine (at the end of a batch, for example) its volume must be made up using cans identical to those being processed, which must be clearly marked and filled with inert material.* The above-mentioned protocol provides detail on the procedures to be adopted by the Official Service during the verification procedures to oversee the activities carried out by the establishments in seeking to produce commercially sterile products: *"*The SIFs operating in these establishments must perform verification of the maintenance of the autoclaves/retorts with the frequency laid down in Internal Standard no. 1/2017, and this verification must necessarily include on-site evaluation of the built facilities, equipment and instruments used in the process. The working of the equipment must also be observed, especially that of the temperature-measuring instruments, the steam equipment and the vents, which must be positioned in such a way as to allow evaluation when the retorts are operating. The total filling of the equipment in accordance with the approved production process description must also be verified. The verification procedures must also take the cooling water for this equipment into consideration within the set of water supply points to be officially verified for their quality,which includes laboratory tests for facultative anaerobes, pH and free residual chlorine, on site.*"*

07	*The regional Inspection Service of Products of Animal Origin (SIPOA) offices do not have direct access to all official microbiological testing results provided by testing laboratories*	To correct this deficiency, the Protocol of Compliance with US Sanitary Requirements (Appendix 2) has been prepared, and in item 3.2 cites the following obligations applying to Federal Inspection Services (SIFs), which must be met immediately: (...). In addition to the above-mentioned controls, the SIF must create a specific case file within the Electronic Information System (SEI), and insert the reports (COAs) for the official microbiological testing for compliance with US requirements on a monthly basis. The case files and documents inserted must adopt the following standardization: • Commence 01 (one) case file per SIF/year to include all the reports • *Iniciar processo* (start case file) -> *Inspeção de Produtos de Origem Animal* (Animal Product Inspection): *Análises Laboratoriais* (Laboratory Analysis) • Specification Official Tests SIF XXXX/YEAR - Nth SIPOA • Classification by topic: 330.3 - *PRODUTOS/INSUMOS PECUÁRIOS* (LIVESTOCK PRODUCTS/INPUTS) • *Interessados* (Interested parties): SIF XXXX • *Nível de acesso* (level of access): *Público* (Target Audience) • *Incluir documento externo* (include external document) • *Tipo de documento* (document type): *Laudo Laboratorial* (Laboratory report) • *Número / Nome na Árvore* (Number/Name in Tree): COA XXX Every month, the case file containing the lab reports (COAs) received by the SIFs must be sent to the SIPOA in question for acknowledgment and management. This is a control that is supplementary to the guidance given in Circular-Memorandum no. 15/2016/CGI/DIPOA/SDA/GM/MAPA, dated 2 March, 2016.”

08	*At the single audited swine slaughter and processing establishment, the establishment personnel were using the m/M criteria to analyze the generic E. coli results from samples collected using the carcass sponge technique. However, the use of the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method*	The Protocol of Compliance with US sanitary requirements was prepared (Appendix 2), and in item 7.2.4, states how the results of samples taken for *E. coli* monitoring in swine carcasses must be managed. The deadline for compliance is immediate: ***II) Management of results*** *Microbiological targets:* *a) Acceptable limit: up to 10 CFU/cm²* *b) Marginal Limit: ≥ 10 and ≤ 10,000 CFU/cm2, where 10 is the lower limit (m) and* *10,000 is the upper limit (M)* *c) Unacceptable limit: > 10,000 CFU/cm²* *It must be stressed that the above-mentioned criteria may only be taken into consideration when the sampling is by the destructive method. If the sampling method used is sponge swabbing, the results must be analyzed by statistical process control techniques.*