USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

FEB 2 0 2020

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, 3º andar, Sala 300
70.043-900 Brasília, DF BRAZIL

Dear Dr. Ribeiro,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a targeted on-site equivalence verification audit of Brazil's meat inspection system from January 13 through January 24, 2020. Enclosed is a copy of the final audit report. The comments received from the Government of Brazil are included as an attachment to the report.

Sincerely,

Michelle Catlin, Ph.D.
International Coordination Executive
Office of International Coordination

Enclosure

FINAL FOLLOWUP REPORT OF AN AUDIT CONDUCTED IN

BRAZIL

JANUARY 13–24, 2020

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 20, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a targeted onsite equivalence verification audit conducted by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) from January 13–24, 2020. The purpose of the audit was to verify the implementation of the Central Competent Authority's (CCA) corrective actions in response to FSIS' June 10–28, 2019 audit findings, and determine whether Brazil's food safety inspection system governing raw and processed meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Brazil currently exports processed beef and pork and raw intact pork to the United States.

The targeted followup audit focused on two system equivalence components which had systemic findings documented in the prior FSIS audit: (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); and (6) Government Microbiological Testing Programs.

The FSIS auditors verified the implementation of corrective actions to the following aspects of the inspection system:

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

- The design and implementation of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection.
- The implementation of post-mortem inspection procedures which 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.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The design and implementation of N60 sampling for Shiga toxin-producing *Escherichia coli* (STEC) by the government inspectors in-plant and testing of these samples by the government laboratories.
- The operation and maintenance of retorts, including accurate retort temperature recording, proper operations to ensure compliance with validated process schedules, design of retorts, 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 FSIS audit confirmed that the CCA has fully implemented the corrective actions described to FSIS to address the prior audit findings within both equivalence components.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY 1

III. BACKGROUND 4

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION) 6

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) 6

VI. COMPONENT THREE: GOVERNMENT SANITATION 8

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM 8

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS 8

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS 8

X. CONCLUSIONS AND NEXT STEPS 11

APPENDICES 12

Appendix A: Individual Foreign Establishment Audit Checklists 13

Appendix B: Foreign Country Response to the Draft Final Audit Report 14

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Brazil's food safety system January 13–24, 2020. The audit began with an entrance meeting January 13, 2020, in Brasília, Distrito Federal, Brazil, during which the FSIS auditors 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 DIPOA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a targeted onsite equivalence verification audit. The audit objective was to verify the implementation and effectiveness of DIPOA's corrective actions in response to the systemic findings identified during the FSIS audit conducted June 10–28, 2019, and determine whether the food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. As a result of the targeted approach of this audit, not all aspects of the DIPOA inspection system were audited.

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.
Raw – Intact	Raw intact beef	Boneless manufacturing trimmings; carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals. (Brazil is currently suspended from exporting these products – see footnote below).

[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.

Raw – Intact	Raw intact meat-other (goat, lamb, and mutton)	Boneless manufacturing trimmings; carcass (including carcass halves or quarters); cuts (including 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	Not ready-to-eat (NRTE) otherwise processed meat (beef, goat, lamb, mutton, pork, and veal)	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.
Heat Treated – Shelf Stable	Ready-to-eat (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.

The USDA Animal and Plant Health Inspection Service (APHIS) recognizes that beef imported from Brazil is subjected to the bovine spongiform encephalopathy requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.18 and/or 9 CFR 94.19. In addition, Brazil is affected with foot-and-mouth disease, except in the State of Santa Catarina, and is subjected to animal health requirements in 9 CFR 94.4; however, raw 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 targeted followup onsite equivalence verification audit, FSIS reviewed and analyzed Brazil's responses to the 2019 FSIS audit findings and supporting documentation. During this targeted followup audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify implementation of Brazil's corrective actions. Determinations concerning program effectiveness focused on performance within the following two equivalence components with systemic audit findings identified in the prior FSIS audit: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); and Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at CCA headquarters, two regional inspection offices, and eight 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. This included confirmation that regional offices maintained direct access to all official microbiological testing results provided by testing laboratories.

A sample of eight establishments from a total of 28 establishments certified to export to the United States were visited. This included seven beef slaughter and processing establishments and one beef processing establishment preparing thermally processed, commercially sterile (TPCS) products. During the establishment visits, the FSIS auditors paid particular attention to verifying the application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection; the implementation of 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 materials (SRM); and verification of the operation and maintenance of retorts.

Additionally, FSIS audited two government microbiological testing laboratories to verify the adequacy of the technical support they provide to the inspection system. The FSIS auditors focused on verifying the analytical procedure used in conjunction with the government verification testing program for Shiga toxin-producing *Escherichia coli* (STEC) in raw beef, as further described under Section IX (Component Six: Government Microbiological Testing Programs) of this report.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Department of Inspection for Products of Animal Origin (DIPOA), Brasília, Distrito Federal
	Regional Inspection Offices	2	• Inspection Service of Products of Animal Origin (SIPOA) offices: – Goiás, Goiânia – São Paulo, São Paulo

Laboratories	2	• Laboratórios Federais de Defesa Agropecuária (LFDA), government microbiological testing laboratories: – LFDA São Paulo, Campinas – LFDA Minas Gerais, Pedro Leopoldo
Beef slaughter and fabrication establishments	6	• Establishment SIF 431, Palmeira de Goiás, Goiás • Establishment SIF 504, Ituiutaba, Minas Gerais • Establishment SIF 1662, Campo Grande, Mato Grosso do Sul • Establishment SIF 2058, Senador Canedo, Goiás • Establishment SIF 4238, Bataguassu, Mato Grosso do Sul • Establishment SIF 4400, Campo Grande, Mato Grosso do Sul
Beef slaughter, fabrication, and processing establishment	1	• Establishment SIF 385, Andradina, São Paulo
Beef processing establishment	1	• Establishment SIF 421, Barretos, São Paulo

FSIS performed the audit to verify the 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.] Section 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 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 included: (a) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (b) 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 December 1, 2016 to November 30, 2019, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 290,321,745 pounds of meat from Brazil. This included 129,946,752 pounds of TPCS beef; 171,200 pounds of ready-to-eat (RTE) fully-cooked beef without subsequent exposure to the environment; 20,524,706 pounds of RTE fully-cooked beef; 63,254,063 pounds of RTE dried beef; 51,999 pounds of RTE acidified / fermented beef (without cooking); 20,235,704 pounds of raw intact beef (prior to suspension of eligibility in June 2017); 562,792 pounds of not ready-to-eat (NRTE) otherwise processed beef; 75,393 pounds of thermally processed, commercially sterile pork; 12,107 pounds of RTE dried pork; and 55,487,029 pounds of raw intact pork exported by Brazil to the United States.

Of these amounts, additional types of inspection were performed on 176,497,823 pounds of meat (91,407,523 pounds of TPCS beef; 171,200 pounds of RTE beef fully-cooked without

subsequent exposure to the environment; 20,479,431 pounds of RTE fully-cooked beef; 18,785,461 pounds of RTE dried beef; 14,331,253 pounds of raw intact beef (prior to suspension of eligibility in June 2017); 412,908 pounds of NRTE otherwise processed beef; 75,393 pounds of thermally processed, commercially sterile pork; and 30,834,654 pounds of raw intact pork). These additional types of inspection included condition of container examinations for TPCS products, and testing for chemical residues and microbiological pathogens (Shiga Toxin-Producing 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, sampling and testing for pathogens of all meat products imported from Brazil to ensure ongoing equivalence in response to a serious trend of violations identified at point-of-entry (POE) during reinspection of Brazilian product. During the period surrounding this increased product examination, FSIS refused entry to over 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. Because of this serious trend of food safety violations and animal health concerns, FSIS suspended the eligibility of raw intact beef from Brazil on June 22, 2017.

Within the current report, the two components that were assessed during this targeted followup onsite audit include a description of the equivalence criteria, the findings from the June 2019, onsite audit, and the FSIS auditors' verification results and observations from this targeted followup audit.

Summary of Verified Findings from the June 10–28, 2019 FSIS Audit of Brazil
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
• The CCA did 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 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 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.
Component 6: Government Microbiological Testing Programs
• The two audited government laboratories were not analyzing the entire N60 sample if the sample submission was greater than the size of the test portion prescribed by the screening method (325 grams (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 SIPOA offices did not have direct access to all official microbiological testing results provided by testing laboratories.

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

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

This component was not assessed during the current followup audit because no systemic audit findings were identified during the previous audit.

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 first of two equivalence components 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.

The FSIS auditors verified the implementation and effectiveness of DIPOA's corrective actions submitted in response to the following findings identified during the 2019 FSIS audit:

- The CCA did 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 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 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.

Verification Results: Temperatures Warranting Condemnation of Livestock During Ante-mortem

In response to the June 2019 FSIS audit, DIPOA developed a document consolidating all specific requirements for export to the United States. This document is entitled *Protocol for Consolidation of Supplementary Requirements for Export to the United States of America* (hereafter referred to as the *Consolidated Protocol for United States Export*). This protocol

effectively updated and replaced approximately 83 official memoranda and inspection circulars specific to United States-export requirements, combining them into a single document.

Within its *Consolidated Protocol for United States Export*, DIPOA has defined the temperatures at which livestock are to be condemned during supplementary examinations related to ante-mortem inspection procedures. These temperatures are equal to those enumerated in 9 CFR 309.3 and used by FSIS with its domestic inspection system. The FSIS auditors verified through interviews and review of clinical examination records that Federal Inspection Service (SIF) veterinarians responsible for conducting ante-mortem inspection were correctly applying these updated requirements.

Verification Results: Implementation of Post-mortem Inspection Procedures

DIPOA has provided additional training to its inspection personnel to address the specific June 2019 FSIS audit findings through a course entitled *Standardization of Ante-mortem and Post-mortem Inspection Procedures for Livestock*. The first phase of training occurred at a central (headquarters) level over a period of eight sessions, spanning from May to September 2019. Phase one attendees included Federal Agricultural Inspectors/Auditors and encompassed all SIF veterinarians permanently assigned to establishments certified to export to the United States. The second phase occurred on an establishment level, during which individuals attending the headquarters session conducted training of SIF Inspection Agents and Inspection Auxiliaries.

During the visit to seven beef slaughter and processing establishments, the FSIS auditors verified that SIF officials performing ante-mortem and post-mortem inspection had received the training as intended. Verification activities included a review of available training certificates, as well as interviews with SIF veterinarians responsible for conducting the training. The FSIS auditors observed and verified that the presentation, identification, examination, and disposition of carcasses and parts ensured correct implementation of post-mortem inspection procedures. The FSIS auditors observed that all instances of the prior deficiencies related to the use of improper manual inspection techniques (e.g., failure to palpate kidneys); presentation of heads; removal of contamination; and proper synchronization of heads, viscera, and carcasses had been resolved.

Verification Results: Control of SRM

Section 6.1.1.7 of the *Consolidated Protocol for United States Export* addresses the control of SRM in beef products exported to the United States. This document corrects errors referenced in the June 2019 FSIS audit report related to the contents of the CCA's *Circular Letter No. 463/2004* and *Memorandum-Circular Letter No. 8/2017*, which had incorrectly defined the distal ileum as having a length of 70 centimeters (with 203.2 centimeters being the intended length). Furthermore, this document requires establishments to institute measures to prevent leakage of brain tissue from the knock hole of cattle during head washing and prohibits the use of head or cheek meat in both raw and heat-processed (i.e., both cooked and TPCS) products destined for the United States.

During the visit to seven beef slaughter and processing establishments, the FSIS auditors verified that these facilities maintained SRM control programs in accordance with the requirements

outlined in the *Consolidated Protocol for United States Export*. This included special emphasis on those elements of control presenting deficiencies identified in the 2019 FSIS audit report. The FSIS auditors observed that each establishment had instituted procedures and provided the necessary employee training to prevent possible contamination of head or cheek meat by brain tissue from cattle during head washing (accomplished by a plastic plug inserted into the knock hole); to ensure proper trimming of lingual tonsils; and to document accurately the identification, removal, and segregation of SRM. The FSIS auditors also reviewed documentation sufficient to demonstrate that government inspection personnel conducted verification of establishment SRM control programs at a minimum of every two weeks, in accordance with DIPOA's written instructions.

Conclusion

The FSIS audit confirmed that DIPOA has implemented the corrective actions described to FSIS that address the June 2019 audit findings related to this component. This included the application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection; the implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and the control of SRM.

VI. COMPONENT THREE: GOVERNMENT SANITATION

This component was not assessed during the current followup audit because no systemic audit findings were identified during the previous audit.

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

This component was not assessed during the current followup audit because no systemic audit findings were identified during the previous audit.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

This component was not assessed during the current followup audit because no systemic audit findings were identified during the previous audit.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The second of two 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 prepared for export to the United States is safe and wholesome. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified the implementation and effectiveness of DIPOA's corrective actions submitted in response to the following systemic findings identified during the 2019 FSIS audit[3]:

- The two audited government laboratories were not analyzing the entire N60 sample if the sample submission was 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 SIPOA offices did not have direct access to all official microbiological testing results provided by testing laboratories.

Verification Results - Analysis of the Entire N60 Sample for STEC

In response to the 2019 FSIS audit findings, DIPOA's section for General Coordination for Laboratory Support (CGAL) issued *Circular No. 10/2019/CGAL/DTEC/SDA/MAPA* to all laboratories conducting STEC analyses in conjunction with United States export. This document specifies that samples weighing more than 325 g ±10 % (i.e., 357.5 g) are to be divided into individual portions and analyzed separately.

During the audit of two government microbiological laboratories, the FSIS auditors observed that these facilities had updated their internal laboratory instructions to meet the requirements of the recently issued *Circular*. The auditors' review of laboratory records indicated that all N60 samples exceeding the 357.5 g threshold were properly processed as "A" and "B" subsamples. The first subsample prepared by the laboratory weighs 325g, with the remaining trim pieces prepared as a second sub-sample. Laboratory records listed the weight of the additional sub-sample and volume of enrichment broth, demonstrating the appropriate weight to enrichment broth ratio of 1:4. All the results were recorded accurately and appropriately for each sub-sample with a final qualitative (i.e., positive or negative) result recorded for the entire sample. The FSIS auditors verified with the CCA that a positive result for one sub-sample would render the entire sample positive.

Verification Results - Verification of the Operation and Maintenance of Retorts

Section 6.2.1.3 of the *Consolidated Protocol for United States Export* addresses the requirements for the maintenance of retorts used to prepare product exported to the United States. This document addresses specific deficiencies identified in the June 2019 FSIS audit report and prescribes requirements to ensure the accuracy of temperature indicating and recording devices; visible operation of all bleeder steam valves; and the prevention of the development of "cold

[3] The previous FSIS audit report also identified a finding concerning the analysis of generic *E. coli* in swine carcasses, for which DIPOA submitted satisfactory corrective actions within its written response. However, onsite verification of corrective actions was not included within the scope of the current audit, which included only beef slaughter and processing establishments.

spots" (which can result in under-processing) during the processing of partial retort batches. As an additional element of corrective actions taken, the DIPOA currently requires SIF personnel assigned to establishments exporting TPCS product to the United States to include a hands-on or direct observation component verification of the maintenance of retorts with the frequency prescribed in *Internal Standard No. 1/2017* (i.e., 10 % of all facility equipment on a fortnightly basis).

During the visit to two establishments preparing TPCS beef products, the FSIS auditors verified that retort operation and maintenance were conducted in accordance with the requirements outlined in the *Consolidated Protocol for United States Export*. Special areas of emphasis included direct observation of the correlation between the temperature-indicating device and the time/temperature recording device; the visibility and operation of bleeder steam valves; and the proper operation of retorts at partial capacity. In all instances, the temperature-indicating devices were at least equal to or within $+0.5^{o}$ centigrade of the time/temperature recording devices, and the correct operation of all bleeder steam valves was easily visible. While one establishment maintained a temperature distribution study to support the processing of partial batches, the FSIS auditors observed that the second establishment used dummy cans filled with inert matter (i.e., cans filled with water) to avoid the formation of "cold spots" when retorts were not filled to validated capacity. The FSIS auditors reviewed SIF inspection records at each facility, for which it was determined that hands-on verification of retort maintenance and operation was routinely performed in accordance with *Internal Standard No. 1/2017.*

Verification Results: Direct Access to Official Microbiological Testing Results by SIPOA

Section 3.2 of the *Consolidated Protocol for United States Export* outlines SIPOA's responsibilities in overseeing the operation of establishments certified to export to the United States. This document includes a set of instructions targeted toward local SIF personnel (i.e., those assigned to individual establishments certified to export to the United States) to ensure the availability of microbiological testing results to SIPOA offices. Specifically, this document instructs local SIF personnel to create monthly case files within MAPA's Electronic Information System that warehouse all received microbiological testing results during that timeframe. The written instructions include a standardized naming convention to help identify the establishment number, type of test conducted, and other relevant information. At the beginning of each month, the SIPOA office reviews the laboratory reports in the case file for the previous month for all establishments under its jurisdiction, and sends acknowledgement to the local SIF personnel upon completion of its review.

During the visit to two SIPOA offices, the FSIS auditors verified that the procedures outlined in section 3.2 of the *Consolidated Protocol for United States Export* were implemented as intended. This included a review of *Salmonella*, *Lm*, and STEC microbiological testing results at one SIPOA office, and *Salmonella* and STEC results at the second location (this office had no establishments producing RTE product for export to the United States under its jurisdiction). No concerns were identified.

Conclusion

The FSIS audit confirmed that DIPOA has implemented the corrective actions described to FSIS to address the June 2019 audit findings related to this component. This included testing of the entire N60 sample when the submission was greater than the size of the test portion prescribed by the screening method (325 g ±10 %); verification of the operation and maintenance of retorts at establishments preparing TPCS products; and direct access to all official microbiological testing results by the SIPOA offices.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on January 24, 2020, in Brasília, Distrito Federal, Brazil, with representatives from the DIPOA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

The FSIS auditors verified the implementation of corrective actions to the following aspects of the inspection system:

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

- The design and implementation of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection.
- The implementation of post-mortem inspection procedures which 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.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The design and implementation of N60 sampling for STEC by the government inspectors in-plant and testing of these samples by the government laboratories.
- The operation and maintenance of retorts, including accurate retort temperature recording, proper operations to ensure compliance with validated process schedules, design of retorts, and implementation of official verification activities to ensure a hands-on or direct observation component.
- The direct access by the regional SIPOA offices to all official microbiological testing results provided by testing laboratories.

The FSIS audit confirmed that the CCA has fully implemented the corrective actions described to FSIS to address the prior audit findings within both equivalence components.

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
JBS S/A Andradina São Paulo	01/16/2020	SIF385	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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	NRTE otherwise processed beef (other); raw intact beef (boneless manufacturing trimmings); RTE dried beef (other - not sliced); and thermally processed, commercially sterile beef (corned (species), and other).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection;
- The control of specified risk materials (SRM); and
- The verification of the proper operation and maintenance of retorts.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/16/2020

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	01/20/2020	SIF421	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	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.	
58.	
59.	

Establishment Operations:	Beef processing.
Prepared Products:	Thermally processed, commercially sterile beef (corned (species), and other).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure the verification of the proper operation and maintenance of retorts.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/20/2020

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	01/21/2020	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	
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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/21/2020

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 Ituiutaba Minas Gerais	01/17/2020	SIF504	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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/17/2020

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 Campo Grande Mato Grosso do Sul	01/21/2020	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.	
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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/21/2020

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 Senador Canedo, Goias	01/22/2020	SIF2058	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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/22/2020

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	01/15/2020	SIF4238	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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/15/2020

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	01/20/2020	SIF4400	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	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, and primals and subprimals).

60. Observation of the Establishment

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

The establishment visit confirmed that DIPOA has implemented the corrective actions described to FSIS to ensure:

- The application of written guidelines that prescribe the body temperature at which livestock are to be condemned during ante-mortem inspection;
- The implementation of post-mortem inspection procedures which ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection; and
- The control of specified risk materials (SRM).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/20/2020

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

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
OFFICE OF THE SECRETARY FOR TRADE AND INTERNATIONAL RELATIONS

Letter n.1/2020

Brasilia, February 12, 2020

Mr. Oliver Flake
Agricultural Counselor
Embassy of the United States of America

Subject: FSIS/USDA Audit Report.

Mr. Counselor,

In reference to Official Letter 016/19, which forwards correspondence from Dr. Michelle Catlin, Food Inspection and Safety Service (FSIS/USDA) and the final audit report proposal from the visit carried out by FSIS in Brazil between January 13 and 24, 2020, please find below the Ministry's comments to the FSIS document:

1. The final audit report proposal indicates that the establishment identified by SIF 4238 is located at the municipality of Bataguassu, *State of São Paulo*. The correct State where the municipality of Bataguassu and SIF 4238 are located is the **State of Mato Grosso do Sul**.
2. The final report proposal also mentions that the course entitled "Standardization of Ante-mortem and Post-mortem Inspection Procedures for Livestock" occurred between *August and October 2019*. The correct period in which the course was carried out is between **May and September 2019**.

I take the opportunity to express the satisfaction of this Ministry with the results of the FSIS audit confirming that the Department of Inspection of Animal Origin Products (DIPOA/MAPA) implemented all corrective actions necessary for regaining equivalence status for the Brazilian Inspection System of Animal Origin Products.

I reiterate MAPA's disposition to continue working in straight coordination with U.S. inspection and safety authorities. I remain at your disposal for any further action needed.

Sincerely,

Orlando Leite Ribeiro
Secretary for Trade and International Relations