



United States Department of Agriculture

Food Safety and  
Inspection Service

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Dear Ing. Guillén,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Argentina's meat inspection system from August 5 through August 22, 2014. Enclosed is a copy of the final audit report. The comments received from the Government of Argentina are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov)

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane Henriques Doherty  
International Coordination Executive  
Office of the Administrator

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
ARGENTINA

August 5 to August 22, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING  
THE PRODUCTION OF MEAT PRODUCTS  
INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

October 28, 2015

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 Food Safety and Inspection Service (FSIS) from August 5 to August 22, 2014. The audit was conducted to verify whether Argentina's food safety inspection system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled. Argentina exports fully cooked not shelf-stable meat (frozen cooked boneless beef) products to the United States. Argentina is not allowed to export raw beef to the United States at this time because of Animal and Plant Health Inspection Service's (APHIS) restriction of Foot and Mouth Disease.

The audit was designed to determine the equivalence of Argentina's meat inspection system and focused on six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. FSIS also verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the last FSIS audit findings conducted from August 22 through September 7, 2012, were being implemented. An examination of Point-of-Entry (POE) findings between October 1, 2012, and April 30, 2014, showed no food safety violations.

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Buenos Aires, six cattle slaughter and boning operations, and one cattle slaughter/boning and processing establishment to verify whether the national system of inspection, verification, and enforcement is being implemented as described by the CCA. Argentina has certified 11 establishments as being eligible to export to the United States. Argentina is exporting frozen cooked boneless beef to the United States.

The FSIS auditor made the following observations that are of concern:

1. Specified Risk Material (SRM), as identified in FSIS regulations (specifically, the dorsal root ganglia (DRG) contained in the vertebral column of cattle 30 months of age and older), was not identified in CCA documentation as requiring removal.
2. Government testing methods for salmonella samples meet the United States criteria. However, the FSIS auditor noted a discrepancy in microbiological testing programs based on the observation of the CCA's use of private laboratories for testing salmonella samples which is inconsistent with the United States criteria that Argentina committed to meet.

FSIS recognizes that because no bone-in beef is currently being exported to the United States, no adulterated product must be removed from United States commerce. FSIS will update the Public Health Information System (PHIS) to restrict eligibility of beef product from Argentina to cooked boneless beef products until the CCA responds to the audit issues with responses that address FSIS concerns.

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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 equivalence verification audit of Argentina's meat inspection system from August 5 to August 22, 2014.

Argentina is eligible to export beef products to the United States. At the time that the audit was conducted, Argentina was not allowed to export raw beef to the United States because of USDA Animal and Plant Health Inspection Service (APHIS) restrictions related to Foot and Mouth Disease. Argentina currently limits exports to frozen cooked boneless beef to the United States. Between October 1, 2012 and April 30, 2014, Argentina exported 3,615,494 pounds of boneless beef products to the United States. A total of 30 pounds was rejected at Point-of-Entry (POE) because of miscellaneous labeling issues.

The audit standards for equivalence determinations include all applicable legislation determined by FSIS as equivalent as part of the initial equivalence process for Argentina, as well as any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement. This audit was conducted pursuant to the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Federal Meat Inspection Regulations (9 Code of Federal Regulations (CFR) Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Points (HACCP) regulations, and
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906).

## **II. AUDIT GOAL AND OBJECTIVES**

FSIS' overall goal for the audit was to verify that Argentina's food safety inspection system governing meat products continues to be equivalent to that of the United States with the ability to produce and export meat products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objectives of determining whether each component continues to be equivalent to that of the meat inspection system of the United States. The six equivalence components are the following: (1) Government Oversight (Organization and Administration); (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Government Chemical Residue Control Programs; and (6) Government Microbiological Testing Programs. FSIS also verified that the corrective actions proffered by the Central Competent Authority (CCA) – the National Service of Animal Health and Agro-Food Quality (*Servicio Nacional de Sanidad y Calidad Agroalimentaria- SENASA*) in response to the 2012 FSIS audit findings are being implemented.

## **III. AUDIT METHODOLOGY**

In conducting this equivalence verification audit, FSIS utilized its routine four-phase process that includes planning, on-site execution, evaluation, and feedback.

The first phase was the in-depth planning phase, involving document and data review of all available information. The auditor began with an analysis of FSIS' previous on-site audit findings to gain information for follow-up examination of the CCA's corrective actions. The FSIS auditor continued examination of the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and self-reporting tool (SRT) data collected by FSIS since the last on-site audit in 2012. FSIS reviewed the current structure of the CCA's inspection system and did not identify any significant changes that have occurred since the last FSIS audit.

During the 2012 audit, no notice of intent to delist (NOID) or delistment was issued. However, the FSIS auditor observed that private laboratories are used for testing *Salmonella* samples, a practice that is not consistent with the written program that Argentina had submitted to FSIS, and upon which FSIS had made an equivalence determination. The FSIS auditor verified that other previous audit findings were corrected, properly documented, and verified as operating effectively.

The second phase was the on-site verification. FSIS verified whether the CCA's oversight activities were adequate through on-site document reviews, interviews, and observations. The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Buenos Aires and seven bovine slaughter/processing establishments to verify that the national system of inspection, verification, and enforcement is being implemented as described by the CCA. During the establishment visits, the auditor paid particular attention to the extent to which the CCA ensures the control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews.

FSIS reviewed data from the chemical residue and microbiology laboratories provided through the SRT. FSIS conducted on-site interviews with inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters and seven audited establishments. In addition, FSIS conducted an on-site audit of the CCA residue and microbiological laboratory in Martinez, Buenos Aires, which is conducting analytical testing as part of Argentina's national residue program and analytical microbiological testing program. FSIS verified the CCA's oversight activities related to the microbiology laboratory through review of available documents at the CCA.

The third phase of the audit was evaluation. The evaluation phase of the equivalence verification audit takes place throughout the entire audit. The FSIS auditors evaluated information throughout audit verification process. The auditors, as well as FSIS management at FSIS headquarters, assessed the results of the evaluations to determine whether the CCA's performance was consistent with the information provided to FSIS, and thereby, whether Argentina remained equivalent to the United States' meat inspection system. The results of the evaluation are discussed in the corresponding sections of this report for each of the system's components.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity to comment on the contents of the report. After reviewing the CCA comments and responses to all findings, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors the resolution of all issues.

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)**

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. The national government of the foreign country must design and administer an inspection system with standards equivalent to those of the system of meat inspection in the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT. The on-site audit included record reviews, interviews, and observations made by the FSIS auditor at government offices, one residue and one microbiological laboratory, and examination of seven United States-certified establishments.

The CCA has the responsibility for implementing Argentina's meat inspection program, including oversight and enforcement of the FSIS regulatory requirements in those establishments certified to export to the United States. The following is the organizational structure from the CCA's headquarters to the establishment's inspection offices:

- *Ministerio De Agricultura, Ganaderia y Pesce* or Ministry of Livestock and Fisheries,
- *Servicio Nacional de Sanidad y Calidad Agroalimentaria Unidad De Presidencia* or SENASA, Presidency Unit,
- *Dirección Nacional de Inocuidad de Calidad Agroalimentaria* or National Directorate of Agrifood Safety and Quality,
- *Dirección de Inocuidad de Productos de Origen Animal* or Directorate Safety of Product of Animal Origin,
- *Coordinación General* or General Coordination,
- Coordination of Processing Establishments; Coordination of Slaughter Establishments; and Coordination of Poultry, Eggs and Game animals,
- *Dirección de Centros Regionales* or Regional Offices,
- Agrifood Safety and Quality,
- An Official Veterinary Inspector assigned at each United States-certified establishment, and
- Official Veterinary Assistants assigned at the United States-certified establishments.

FSIS verified that Ministry of Agriculture, Livestock, and Fishery oversees the SENASA, which manages Argentina's Meat Inspection Service. SENASA provides delivery of services in the field and is responsible for the safety of meat products and the promulgation of food safety regulations, as well as enforcing the laws and regulations of meat product inspection system.

The FSIS auditor interviewed the CCA officials at the headquarters and requested records related to implementation of corrective actions as applicable to FSIS 2012 audit findings. The auditor confirmed that the CCA had verified the implementation and effectiveness of the corrective actions.

The FSIS auditor interviewed the inspection personnel assigned to the audited establishments and verified the implementation of Argentina's Ministry of Agriculture and Livestock, Executive Decree No. 4.238, Chapter II, (2.1.1) and (2.2.27), which requires that the CCA maintain a single standard of laws and regulations applicable to all establishments certified for export to the United States.

FSIS noted that the inspection verification activities are conducted in a consistent manner at all seven of the audited establishments in accordance with uniform instructions distributed from the CCA to the field via email, fax, telephone, and hard copies. The CCA publishes and disseminates updates and additional instructions to inspection personnel concerning revised regulations or export requirements. These Circulars contain procedures to ensure that inspection personnel are applying a single standard of inspection while verifying the adequacy of food safety measures implemented at the United States-certified establishments. The CCA headquarters receives acknowledgement from regional offices and establishments upon receipt of these Circulars as applicable at all levels.

During the headquarters audit, the FSIS auditor verified that the meat inspection program is funded from the national funds according to the Act 25.641, "National Institute of Agricultural Technology." The CCA deposits salaries from appropriated funds in employees' personal bank accounts. Each employee receives a salary receipt issued by the CCA. The CCA inspection officials shared the above information with the FSIS auditor and presented some of their receipts issued by the CCA.

The CCA's headquarters staff performs initial and on-going certification of establishments for export to the United States. The CCA's Executive Decree No. 4238 of 1968 Chapter 30 describes regulatory requirements for sanitation, and Circular No. 3343 describes the regulatory requirements of HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), humane handling and slaughter requirements, and generic *E. coli* testing methodology. Those establishments that manufacture products intended for export to the United States are required to comply with the conditions and requirements of the country of destination or equivalent conditions and requirements in accordance with the CCA's Executive Decree No. 4238, Chapter 1 (1.1.4.1), "Conditions or requirements for export." The FSIS auditor reviewed HACCP and SSOP programs developed by all seven establishments audited. The auditor also reviewed the humane handling and generic *E. coli* programs developed by all seven slaughter establishments.

The CCA has the authority to require corrective actions in the United States-certified establishments and to take additional enforcement measures as appropriate in accordance with the CCA's Executive Decree No. 4238. On October 7, 2011, the CCA delisted establishment No. 13 because of FSIS' notification for a second POE violation because of ivermectin. This establishment remains ineligible to export to the United States in 2014. The CCA's verification

of ivermectin controls and further actions are addressed in the Chemical Residues Control Programs section of this report.

The FSIS auditor verified that the CCA's Executive Decree No. 4238, Chapter VIII (8.1.1) is being implemented in the audited establishments. This Decree requires that official veterinarians and assistants implement the hygienic and sanitary surveillance of establishments.

The CCA has an ongoing plan to continuously analyze and implement staffing requirements. The FSIS auditor verified that the inspection program's staffing in the audited establishments is in accordance with the CCA's Executive Decree No. 4238, Chapter VIII, "Official personnel/Veterinary inspection."

The CCA provides training to its inspection personnel in accordance with the CCA's Executive Decree No. 4238, Chapter VIII. The CCA maintains a copy of all the training records and certificates. The FSIS auditor reviewed a sample of the training records and certificates during the on-site audit of the CCA headquarters' inspection offices in each audited establishment and residue and microbiological laboratories visited.

During the on-site audit of the Buenos Aires region government office, the FSIS auditor interviewed the regional inspection personnel and thematic coordinators and reviewed inspection documents including the regional organizational chart. There are 14 regions with regional directors and four thematic coordinators in each region.

The CCA has the legal authority and responsibility to approve or disapprove laboratories conducting analytical testing of products for export to the United States. The FSIS auditor verified that the audited establishments are using private laboratories that are approved by the CCA-DILAB for testing of carcasses for *Salmonella*. The collection of samples for *Salmonella* is performed by the CCA. Establishment personnel perform the collection of samples for generic *E. coli* testing. However, the auditor also noted a discrepancy in microbiological testing programs because the CCA's use of private laboratories for testing *Salmonella* samples is inconsistent with the United States criteria that Argentina committed to meet.\*

The document analysis and on-site audit verification included observations, document reviews, and interviews in combination with document analysis of the CCA's control measures. The audit confirmed that Argentina's meat inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing meat inspection in official establishments. However, as noted above, the findings in the government microbiological testing program components evidence that the CCA needs to improve how it does microbiological testing. With this exception, the verification activities of Argentina's inspection system as designed and implemented showed that the CCA has the ability to meet equivalence requirements for this component, as articulated by the FSIS import regulations (9 CFR 327.2). FSIS has determined that Argentina's inspection system and the CCA continue to demonstrate the ability to meet the core equivalence requirements for this component and operates at an "adequate" level of performance.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. To be considered equivalent to FSIS' program, the inspection system must be designed and administered by the national government of the foreign country. The system must provide for humane handling and slaughter of livestock; ante-mortem inspection of animals or birds; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; and daily inspection and periodic supervisory visits to official establishments.

The FSIS auditor interviewed the inspection personnel at the CCA's headquarters and seven audited establishments. The inspection personnel are employees of the national government. There are no regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA. The auditor noted that the CCA implements its inspection of meat and meat by-products in accordance with Acts No. 3959 and 11.226. The FSIS auditor reviewed inspection documents generated within the last 3 months. The review verified that the inspection personnel perform daily inspection verification activities concerning HACCP, SSOP, and SPS requirements in audited establishments.

The FSIS auditor reviewed the CCA's Executive Decree No. 4238, Chapter X, Ante-mortem inspection rules. The auditor also reviewed ante-mortem inspection records generated by the inspection personnel in the seven slaughter establishments audited. In addition, FSIS observed ante-mortem inspection examination. The auditor verified that the inspection personnel follow the CCA's regulatory requirements. There are no regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

The FSIS auditor reviewed the CCA's Executive Decree No. 4238, Chapter XI, Post-mortem examination. The auditor also reviewed post-mortem inspection records generated by the inspection personnel in the seven audited slaughter establishments. In addition, FSIS observed post-mortem inspection synchronization and examination of carcasses, viscera, and heads as well as disposition and retention/condemnation procedures at the time of slaughter. The auditor verified that the inspection personnel follow the CCA's regulatory requirements. There were no concerns with post-mortem procedures.

The CCA's Executive Decree No. 4238, Chapter II (2.1.1) provides the legal authority for the CCA's oversight controls over each establishment's construction, facilities, and equipment. During each establishment's audit, the FSIS auditor verified that the audited establishments are complying with the provision of these documents while the inspection personnel enforce the applicable requirements.

The CCA's Executive Decree No. 4238, Chapter III (3.4), Circular No. 3580, and Circular No. 3528 provide the legal authority for the CCA's oversight over condemned materials until they

are removed or destroyed. The FSIS auditor noted that the inedible and condemned product containers were properly labeled and color-coded. The audited slaughter and processing establishments have rendering facilities that are operated by the establishments. The FSIS auditor reviewed inspection verification records “Daily Condemned Bovine Records” concerning the disposition of the condemned products.

The document analysis and on-site audit verification including observations, document reviews, and interviews in combination with document analysis of the CCA’s control measures demonstrate that the CCA meets FSIS equivalence core criteria at an “average” level of performance.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS’ program, the CCA must provide equivalence requirements for all areas of sanitation, sanitary handling of products, SPS, and SSOP. The FSIS auditor verified that the inspection personnel at the seven audited establishments conduct verification of sanitary conditions in accordance with the following requirements:

- Executive Decree No. 4238 (The Regulations for the Inspection of Products of Animal Origin, By-Products, and Derivatives),
- Executive Decree No. 4238, Chapter III (Sanitary Building and Engineering of Slaughter Establishment),
- Executive Decree No. 4238, Chapter XXXI (Good Manufacturing Practices and Standard Operating Procedures),
- Circular No. 3837 (Supplement to Circular No. 3271/97 – Company SSOP Implementation Procedures and Verification by the Veterinary Inspection Services),
- Circular No. 3297 (Guidelines for SSOP Evaluation and Verification - Pre-Operational and Operational Guidelines),
- Circular No. 3271 (Implementation of Sanitation Standard Operating Procedures by the establishments), and
- Circular No. 3259 (Future Application of the SSOP in the United States Establishments)

This information supports that the CCA has the legal authority and responsibility to require that each certified establishment develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditor reviewed each audited establishment’s sanitation program and records generated within the last 90 days. The auditor did not identify any concerns.

The FSIS auditor assessed the verification activities performed by inspection personnel by reviewing their verification records for each establishment’s pre-operational and operational sanitation monitoring. In addition, the auditor observed the inspection personnel as they performed pre-operational and operational sanitation inspection verification. FSIS verified that the inspection personnel conduct pre-operational and operational sanitation verification on a daily basis as required by the CCA. The record review confirmed that the inspection personnel identify and document their observations in an equivalent manner to FSIS system.

The document analysis and on-site audit verification, including observations, document reviews, and interviews, demonstrate that the CCA meets FSIS equivalence core criteria at an “average” level of performance, while corrective action was performed immediately, when needed.

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

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or an equivalent preventive control plan. The CCA’s headquarters and seven establishments were audited to verify whether the CCA maintains effective government oversight for the implementation of the CCA's meat inspection system and, in particular, HACCP requirements. The evaluation of this component included an analysis of the responses provided by the CCA in the HACCP portion of the SRT. The documents reviewed included:

- Circular No. 3531 (Updates for generic *E. coli* control; *E. coli* O157:H7 in trimmings or ground meat; *Salmonella* Control/Pathogen Reduction Program; HACCP compliance verification),
- Circular No. 3514 (*E. coli* O157:H7 as a Reasonable Hazard in the HACCP Plan) is based on FSIS Notice 44-02 from 11/04/02 for “Instructions for setting out verification of *E. coli* O157:H7.”
- Circular No. 3390 (Checklist for Certification of Export Products); Circular No. 3353 (HACCP System- Basic Compliance Checklist), and
- Circular No. 3259 (Future Application of the HACCP in the United States’ Establishments).

The FSIS auditor conducted on-site observations to assess the establishments’ operations and the inspection verification in accordance with the aforementioned requirements.

The FSIS auditor conducted on-site observations to assess whether the CCA was consistently implementing an inspection and verification system the establishments’ operations and the inspection verification in accordance with the aforementioned requirements and that the establishments were, in fact complying with the CCA requirements for production of product for the United States. The FSIS auditor confirmed that the inspectors were establishments are conducting daily verification that establishments met HACCP requirements, including verifying that establishments maintain written HACCP programs, verifying that establishment conducts monitoring, verification, corrective actions, and record keeping. Inspectors also conduct hands-on verification that processes meet critical limits at critical control points (CCPs) during all production shifts. No concerns were noted.

FSIS verified that the inspectors verified that establishments maintained documentation that includes HACCP flow charts, written hazard analysis, and associated documents that support decisions made to establish CCP’s and critical limits. Similarly, as noted above, inspectors verified that establishments also generate and maintain records documenting the results of CCP monitoring activities and implement corrective actions when deviations occurred for which the CCA was verifying. No concerns were noted.

However, importantly, FSIS observed that the CCA did not ensure that all the Specified Risk Material (SRM) identified in FSIS regulations were identified in CCA documentation, specifically the dorsal root ganglia (DRG) contained in the vertebral column of cattle 30 months of age and older.\* Meanwhile, the CCA has clarified to FSIS that, at this time, only boneless beef is being exported to the United States and, thus, the DRG is not an issue of concern to the CCA. FSIS does not agree.

Until the SRM issue is resolved satisfactorily with FSIS, the status of the Argentina equivalence is under consideration by FSIS. FSIS recognizes that because no bone-in beef is currently being exported to the United States, no adulterated product must be removed from United States commerce. Meanwhile, until FSIS has affirmed the CCA response as being adequate, FSIS will update the Public Health Information System (PHIS) to restrict eligibility of beef product from Argentina to boneless beef products only.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAMS**

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

The FSIS auditor verified that the CCA has a Residue Control and Food Hygiene plan, organized and administered by the national government, that includes random sampling of internal organs and fat of carcasses for chemical residues. The 2014 residue-sampling plan was being followed by the inspection personnel as intended in all seven establishments audited.

The CCA had taken appropriate corrective actions for the verification of ivermectin because of the 2011 POE violations and issued the CCA Circular Letter No. 3980, dated December 29, 2011. This Circular is being implemented in the United States-certified establishments.

The Circular 3980 A, dated August 21, 2012, informs that "Cooked Products Exportation to USA" requires that establishment be in charge of collecting samples of every "production batch" under the supervision of the Service for Veterinary Inspection, awaiting a negative result for their certification to the United States. According this Circular, establishments are required to test every production lot that is cooked, while SENASA tests for ivermectin in fresh product. The FSIS auditor confirmed that the instructions of the Circular were implemented as described.

There have not been any POE violations for ivermectin in Argentina since the last United States audit in September 2012.

The FSIS auditor visited the “General Directorate of Laboratories and Technical Control” chemical residue laboratory located in Martinez. The auditor reviewed training records and certifications associated with the qualifications of the analysts. The on-site document reviews indicate that the laboratory analysts had successfully completed intra-lab and inter-lab evaluations administered by the laboratory supervisor and possessed the competencies necessary to conduct the analysis assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the CCA requirements.

The document analysis and on-site audit verification including observations, document reviews, and interviews demonstrate that the CCA meets FSIS equivalence core criteria at an “average” level of performance.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are unadulterated, safe, and wholesome and meet all equivalence criteria. The FSIS auditor assessed the implementation of the microbiology laboratory’s policies and procedures based on information obtained from interviews of inspection officials during the headquarters, regional office, and establishment visits. The FSIS auditor verified that the laboratory provides training to its analysts and functions as a reference laboratory that is in contact with other reference laboratories around the world. The ISO 17025 program was implemented in 2004 with 45 accredited methods approved.

The CCA has adopted the FSIS regulatory requirements for testing for generic *E. coli* and issued the CCA Circular No. 3259/96. The FSIS auditor reviewed the written generic *E. coli* program and the records of analytical testing results produced by the establishments for the previous 90 days. The auditor also observed the quality control program employees collecting the sample from chilled beef carcasses using the aseptic sampling techniques at both slaughter/processing establishments. These reviews and observations indicate that all seven of the audited establishments are meeting the CCA’s regulatory requirements for testing for generic *E. coli*. No concerns were noted.

The CCA has adopted the FSIS *Salmonella* standards for raw intact beef meat products. The CCA issued Circular No. 3764, dated September 21, 2007, “*Salmonella* testing for the United States.” The establishments were evaluated according to the CCA’s regulatory requirements. The FSIS auditor verified that the sampling methodology is in accordance with the CCA requirements including corrective or enforcement actions as appropriate. *Salmonella* samples are

analyzed in the NETWORK of private laboratories certified and authorized by DILAB. The FSIS MLG 4.04 method is used for carcass sponging *Salmonella* testing.

The auditor also noted a discrepancy in microbiological testing programs because of the CCA's use of private laboratories for testing *Salmonella* samples, which is inconsistent with the United States criteria that Argentina committed to meet. Additionally, this concern was identified in the 2012 audit and has not been corrected. FSIS needs a response from the CCA within 60 days to support and demonstrate that their testing method of salmonella samples meets the United States criteria.

The CCA has adopted FSIS regulatory requirements for the control of *Listeria monocytogenes* (*Lm*) and *Salmonella* in post-lethality exposed RTE products. The only audited processing establishment producing RTE (frozen cooked beef) product is meeting the CCA's regulatory requirements by adopting alternative three for the control of *Lm* in its product.

The Circular 3555, which was introduced to the inspection field operation personnel in August 22, 2003, under the name "Control for *Listeria monocytogenes* in Ready-to-Eat products (RTE) to be exported to the USA" and Circular Letter No. 3992-12, dated May 2, 2012, dealt with products that have been exposed to the environment following post-lethality treatment and included three options:

1. Apply post-lethality treatment and inhibition of *Lm* growth treatments in the product. Verification controls are required for validation of post-lethality treatment.
2. Apply one of the procedures mentioned in point 1 above. In this case, verification activities must be performed on a more frequent basis.
3. Apply sanitation measures, which require more active and frequent verification activities.

The CCA product verification samples for *Lm*, *Salmonella*, and *E. coli* O157:H7 were found to be negative for calendar year 2014. No concerns were noted.

In August 31, 2011, SENASA published in Circular 3961 the FSIS document "FSIS-USDA-Equivalence Criteria (Control program for *Listeria Monocytogenes* in Ready-to Eat Product". The document requires that all establishments manufacturing meat and poultry ready-to-eat (RTE) products without post-lethality exposure (e.g., cooked in a bag or thermally processed) and meat RTE products with post-lethality exposure prevent product adulteration by the presence of the pathogenic bacterium *Lm*. All RTE products must comply with the requirements for lethality. Furthermore, establishments manufacturing products with post-lethality exposure are required to adopt control alternatives in their HACCP plan or SSOP or other pre-requisite programs to prevent product adulteration by *Lm*. The Network of Government approved laboratories are using MLG 8.09 method for detection of the *Lm* and MLG 4.08 method for detection of *Salmonella* in RTE meat.

The government laboratory analyzing RTE product for *Lm* and *Salmonella* uses the FSIS MLG 8.09 method for detection of *Lm* and MLG method 4.08 for detection of *Salmonella* in RTE meat product.

When positive results for *Lm* are found in cooked products resulting from the sampling plan established by Circular Letter 4066/13, the methodology developed in Circular Letter 4063 of

January 24, 2013, dealing with “Sampling in salt cured products and cold cuts for microbiological control and verification of labels” is to be implemented, which was verified by the FSIS auditor.

The Circular Letter 4008 was published to announce the USDA/FSIS requirements for verification of Shiga Toxin Producers in addition to *E. coli* O:157:H7 (FSIS NOTICE No. 40/12) of June 25, 2012, requiring that:

1. Establishments shall reassess their HACCP Plans adding, besides *E. Coli* O157:H7, the following toxin-producing serogroups as biological hazards: SHIGA (O26, O45, O103, O111, O121 and O145) as adulterants of non-intact raw products and components of other products.
2. This should be taken into account when analyzing the trimming samples collected during deboning under the provisions of the HACCP Plan, after their inspection by the HACCP team.
3. The Service for Veterinary Inspection and the Supervisor shall verify and record that the Company adopts this measure.
4. The result of the analysis should be considered “non-acceptable” if the result is positive for any of the above-mentioned serotypes, including *E. coli* O157:H7.

The document analysis, observations made during on-site establishments’ visit including, document reviews, and interviews conducted at all audit locations demonstrate that FSIS has concerns related to the CCA level of performance. FSIS needs a response from the CCA within 60 days to support and demonstrate that their testing method of salmonella samples and *E. coli* STEC government testing meets the United States criteria.

## **X. CONCLUSIONS AND NEXT STEPS**

In conclusion, the audit results demonstrate that Argentina’s inspection system is performing at an “adequate” level in maintaining its equivalence. The CCA meets established core criteria for all six equivalence components; however, the audit observations indicate concerns that require immediate improvement. These observations were conveyed by the FSIS auditor to the CCA inspection personnel at an exit meeting on August 22, 2014, in Buenos Aires.

1. Specified Risk Material as identified in FSIS regulations; specifically the dorsal root ganglia contained in the vertebral column of cattle 30 months of age and older, was not identified in CCA documentation as requiring removal.
2. Government testing methods for salmonella samples meet the United States criteria. However, the FSIS auditor noted a discrepancy in microbiological testing programs because of the CCA’s use of private laboratories for testing salmonella samples which is inconsistent with the United States criteria.

FSIS recognizes that because no bone-in beef is currently being exported to the United States, no adulterated product must be removed from United States commerce. FSIS has affirmed that the audit identifies Argentina as being adequate. FSIS will update the Public Health Information System to restrict eligibility of beef product from Argentina to cooked boneless beef products until the CCA responds to the audit issues with responses that address FSIS concerns.

# APPENDICES

**APPENDIX A: Individual Foreign Establishment Audit Checklist**

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

<b>1. ESTABLISHMENT NAME AND LOCATION</b> Frigorifico Rioplatense S.A.I.C.I. y F. Av. De los Constituyentes 2801 B1617AAAn-GRAL. PACHECO – BS. AS	<b>2. AUDIT DATE</b> 08-07-2014	<b>3. ESTABLISHMENT NO.</b> 1920	<b>4. NAME OF COUNTRY</b> Argentina
		<b>5. NAME OF AUDITOR(S)</b> Oto Urban	<b>6. TYPE OF AUDIT</b> <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 8/7/14 Est. Est. 1920: S/B

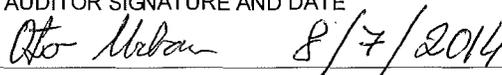
39/51 In the boning room, during the pre-operational sanitation, the auditor noted that there were three cracks in the metal material of processing tables in the boning area which are difficult to clean and establishment needs to ensure thorough cleaning as well to ensure that their use will not cause the product contamination and adulteration.

18/58/51 The FSIS auditor observed that the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION ARRE BEEF S.A. Est.of.N°2082 RioParana901-PerezMillan-Ramello PeiaBsAs.	2. AUDIT DATE 08-08-2014	3. ESTABLISHMENT NO. 2082	4. NAME OF COUNTRY Argentina
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/08/14 Est. 2082 ARRE BEEF S.A., S/B

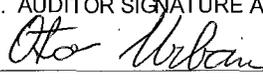
18/58/51 The FSIS auditor observed that the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

10/51 The FSIS Auditor observed deep cut in the conveyor belt at the boning processing area. This belt was moving edible product which was in contact with the exposed belt fabric. Establishment officials claimed that they were in the process of replacing the belt for the last five days.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

 8/8/2014

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION F.R.I.A.R. S.A. Bv.Hipolito Irygoyen 298 (3560) Reconquista (Santa Fe) Argentina	2. AUDIT DATE 08-12-14	3. ESTABLISHMENT NO. 1970	4. NAME OF COUNTRY Argentina
		5. NAME OF AUDITOR(S) Dr. Oto Urban	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/12/14 Est. 1970 F.R.I.A.R. S.A. S/B

38 The entering door to the boning room had space under the door permitting insect entering the area. This deficiency was immediately corrected by replacing the old rubber with the new one and covering the open space.

46 During the on-site audit, the non-dripping condensation over the carcasses was observed in the cooler. This non-compliance was immediately corrected by the removing carcasses from affected area and cleaning/removing the condensation.

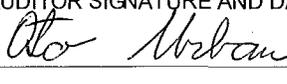
18/58/51 The FSIS auditor observed that the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

54/51 the FSIS auditor observed during the on-site audit of the ante-mortem facilities and procedures that the suspect pen was the missing the light which enables the inspection of suspect animal during the early and late hours. This non-compliance was scheduled for corrective action by the inspection service and establishment.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

 8/12/2014

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION FRIAR S.A. Lisandro De La Torre 810 Nelson-Santa Fe	2. AUDIT DATE 8/13/2014	3. ESTABLISHMENT NO. 249	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/13/2014 Est #: 249 [S/B] (Argentina)

18/58/51 The FSIS auditor observed that the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

10 The FSIS auditor observed that some of the moving carcasses were observed in the contact with the employee's stand in the post-mortem inspection/trimming area. This non-compliance was immediately corrected by moving the employee stands away from the carcass flow.

61. NAME OF AUDITOR

Oto Urhan DVM

62. AUDITOR SIGNATURE AND DATE

*Oto Urhan* 8/13/2014

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Compania Bernal s.a. Bernal Oeste-Buenos Aires, Argentina	2. AUDIT DATE 08/14/2014	3. ESTABLISHMENT NO. 2062	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/14/2014 Est #: 2062 [S/B] (Argentina)

10/51 The FSIS auditor observed that the employee in the post-mortem trimming area was picking up the fallen trimmings from the floor with the hand and the hook and contacting carcasses without changing his gloves. This employee was immediately reprimanded and scheduled for re-training. The carcass was separated for trimming corrective action procedure.

52/51 The FSIS auditor observed during the tour of the cattle stunning operation, that ineffective stunning operation was performed by the establishment employee. The SENASA inspection officials asked the establishment to revise the animal fixing device and slow down the stunning operation.

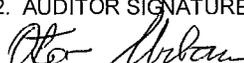
46 The FSIS auditor observed that two damaged (by forklift) boxes were in the freezer. The immediate corrective action was performed by checking the product and re-packaging the boxes.

18/58/51 In the post-mortem department, the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

61. NAME OF AUDITOR

Oto Urhan, DVM

62. AUDITOR SIGNATURE AND DATE

 8/14/2014

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION S.A. Importadora y Exportadora de la Patagonia Est. No Official 189 Ruta 191 Km 94.5 Salto (Bs.As)	2. AUDIT DATE 08/15/2014	3. ESTABLISHMENT NO. 189	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/15/2014 Est #: 189 [S/B] (Argentina)

18/58/51 The FSIS auditor observed that the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

58 The FSIS auditor observed that a knife used for the SRM tonsil removal needs to be identified by different color or shape than knife used for non-SRM material. This non-compliance was corrected immediately by the establishment management.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

*Oto Urban* 8/15/2014

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Frigorifico "Gorina." S.A.I.C. Calle 501 s/n - Joaquin Gorina La Plata Buenos Aires Region	2. AUDIT DATE 08/19/2014	3. ESTABLISHMENT NO. 2025	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

46 The FSIS auditor observed, during the on-site that pieces of a dry cohesive material keeping the wall particles together were hanging over the carcass cooler entrance door over the entering for half carcasses. This deficiency was corrected immediately by the establishment officials.

18/58/51 In the post-mortem department, the process of removal of SRM was performed by the removal of only brain, eyes, tonsils and spinal cord but not additional SRM which are addressed in the SRT and identified as SRM material in Circular No. 3580.

58 The FSIS auditor observed that a knife used for SRM spinal cord removal needs to be identified by color or shape-this non-compliance was corrected immediately. This deficiency was scheduled for corrective action.

61. NAME OF AUDITOR  
Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

*Oto Urban* 8/19/2014

**APPENDIX B: Argentina's Response to Draft Final Audit Report**

10.09.2015  
Y.



Ministerio de Agricultura, Ganadería y Pesca  
Servicio Nacional de Sanidad y Calidad Agroalimentaria  
Coordinación de Relaciones Internacionales

NOTA CRI N° 348 / 2015

<b>Para:</b>	DR. SHAUKAT H. SYED
<b>Institución:</b>	DIRECTOR INTERNATIONAL AUDIT STAFF FSIS
<b>C.c.:</b>	CONSEJERÍA AGRÍCOLA DE ESTADOS UNIDOS EN BUENOS AIRES
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<b>Institución:</b>	CONSEJERÍA AGRÍCOLA ARGENTINA EN ESTADOS UNIDOS
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<b>e-mail:</b>	relint@senasa.gov.ar
<b>Total de páginas:</b> (Incluye la cubierta)	3 (tres)

**ASUNTO: ESTADOS UNIDOS – FSIS: Borrador Final de la Auditoría realizada por FSIS – Respuesta de SENASA al Ítem X –**

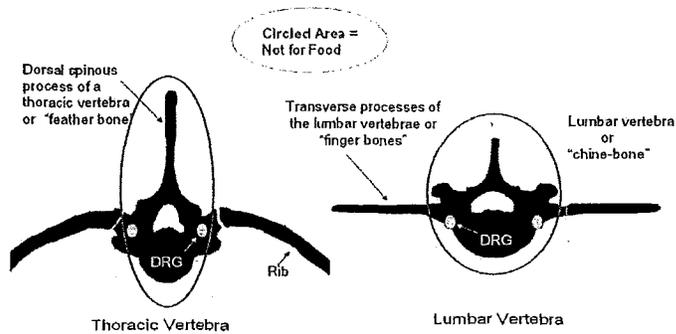
**Prioritario**

Por medio de la presente, tengo el agrado de dirigirme a Usted, a efectos de **dar respuesta al Ítem X** del Informe Borrador de la Auditoría realizada por FSIS entre el 05 y el 22 de agosto de 2014.

Al respecto, desde Enero de 2004 a través de la Circular 3580, se prohíbe el uso de material considerado de riesgo en la elaboración de productos con destino a los Estados Unidos, citándose los mismos: cráneos, sesos, ojos, ganglios trigéminos, médula espinal, columna vertebral (excluida cola, procesos transversos de vértebras torácicos y lumbares y alas del sacro), raíces de los ganglios dorsales (que se hallan contenidos en las vértebras), tonsilas, intestino delgado (última porción: ílium)

Luego de la faena, las medias reses pasan a la sala de cuarteo y/o despostada. En esta última se remueve la columna vertebral y con ella se eliminan las raíces de los ganglios dorsales como lo muestra el siguiente esquema:

Schematic Cross-section of SRM Vertebrae.



Por otro lado, como fundamento para el levantamiento de la no conformidad descrita en el ÍTEM 2 que indica:

*"Los métodos de pruebas del gobierno para las muestras de Salmonella cumplen con los criterios de los Estados Unidos. Sin embargo, el auditor del FSIS observó una discrepancia en los programas de pruebas microbiológicas debido al uso por parte de la ACC de laboratorios privados para el estudio de las muestras de Salmonella que no es coherente con los criterios de los Estados Unidos."*

En este sentido, se adjunta un documento conforme los requerimientos realizados por el Dr. Andreas KELLER, para evaluar la equivalencia de Sistemas de Control antes mencionado.

Se adjunta traducción de cortesía.

Sin otro particular, lo saludo muy atentamente.

*med*

Lic. Valeria **FERRÉ**  
Coordinadora de Relaciones  
Internacionales  
SENASA

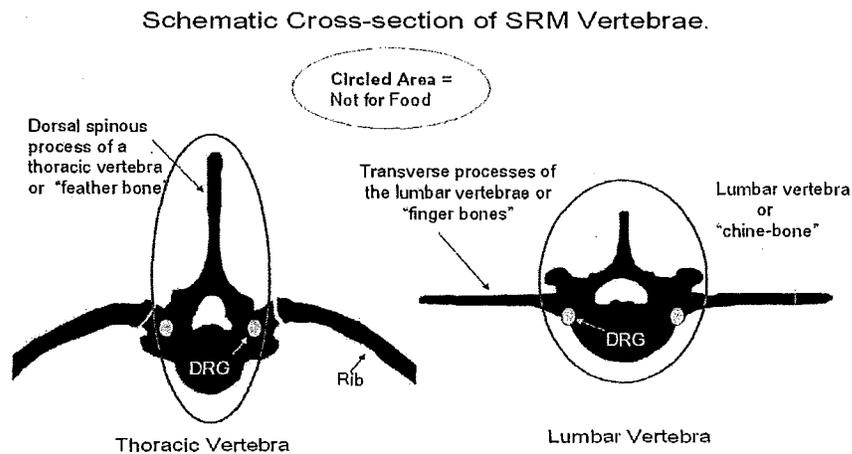
**Courtesy translation**

By means of this letter, I am pleased to address you for the purposes of **responding Item X** of the Draft Report of the Audit conducted by FSIS on August 5-22, 2014.

In this respect, since January 2004 by means of Circular Letter 3580, the use of risk materials has been prohibited in the manufacture of products intended for the United States, which include: skulls, brains, eyes, trigeminal ganglia, spinal cord, backbone (excluding the tail, transverse processes of thoracic and lumbar vertebrae, and wings of the sacrum), dorsal ganglia roots (contained in vertebrae), tonsils, small intestine (last part: ileum).

After slaughter, half carcasses enter the quartering and deboning room.

At this latter stage, the backbone is removed, disposing with it the dorsal ganglia roots as shown in the following diagram.



On the other hand, as the grounds for lifting the non-compliance described in ITEM 2 where the following is stated:

*"The testing methods of the government for Salmonella samples comply with the criteria of the United States. However, the FSIS auditor identified a discrepancy in the microbiological testing programs due to the use of private laboratories for the study of Salmonella samples by the CCA, which is not consistent with the criteria of the United States."*

In this respect, **a document** is attached pursuant to the requests made by Dr. Andreas KELLER to evaluate the equivalence of Control Systems referred to before.