USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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AUG 0 1 2017

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Ministerio de Agricultura, Ganaderia, Pesca y Alimentación
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Dear Dr. Dillon,

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Argentina's inspection system from November 29 through December 13, 2016. 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.

FSIS is reviewing the proposed corrective actions received from the Central Competent Authority (CCA) to address findings identified during the 2016 audit. FSIS also will be requesting additional information pertaining to Argentina's raw beef products inspection system. FSIS will review Argentina's submitted corrective actions and submitted documentation, including relevant supporting documents, to determine whether Argentina's raw beef products inspection system is equivalent.

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

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

ARGENTINA

NOVEMBER 29 TO DECEMBER 13, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 28, 2017
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite audit conducted by the Food Safety and Inspection Service (FSIS) from November 29 to December 13, 2016. The purpose of the audit was to verify that Argentina's food safety system governing the production of processed beef products continues to be equivalent and that products eligible to export to the United States are safe, wholesome, unadulterated, and accurately labeled and packaged. An additional objective of the audit was to assess Argentina's regulatory oversight of raw beef (fresh/frozen) products to determine if the meat inspection system is equivalent and can be reinstated. Argentina currently exports only processed beef products to the United States.

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

An analysis of each component did not identify any systemic findings representing an immediate threat to public health. However, the FSIS auditors identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS

- The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions which could lead to product contamination. This finding was also noted during the FSIS audit conducted in 2012.

GOVERNMENT SANITATION

- In four of five audited establishments, the FSIS auditors observed findings related to requirements of Sanitation Performance Standards (SPS). SPS findings are noted in the respective establishment checklists provided in Appendix A of this report. The National Service of Animal Health and Agro-Food Quality delisted one of the audited establishments that posed a potential for product contamination.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- In one establishment, the HACCP plan's critical limit was not supported. A review of the written HACCP plan demonstrated the critical limit for controlling *Clostridium perfringens* did not include a procedure to monitor the temperature of the product; it only included a timeframe. The Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) (Appendix B) was utilized as support for the critical limit. Appendix B outlines the need for a time and temperature relationship to control the outgrowth of Clostridium spores.

During the audit exit meeting, the Central Competent Authority (CCA) committed to begin to address the preliminary findings as presented. FSIS will further assess the equivalence of Argentina's meat inspection system upon receiving the CCA's proposed corrective actions for the reported findings.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Argentina's food safety system from November 29 to December 13, 2016. The audit began with an entrance meeting held on November 29, 2016, in Buenos Aires with the participation of representatives from the Central Competent Authority (CCA) – The National Service of Animal Health and Agro-Food Quality (SENASA) and two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence audit for processed beef products in conjunction with an audit for reinstatement of equivalence for raw beef products. The audit objective was to ensure the food safety system governing processed and raw beef products is equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The scope of this audit included all aspects of Argentina's inspection system for producing and exporting raw and processed beef products to the United States.

The FSIS auditors applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe, in addition to information obtained directly from the CCA through a self-reporting tool (SRT).

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

Administrative functions were reviewed at CCA headquarters, one regional office, and five local inspection offices located within the audited establishments, during which the FSIS auditors evaluated the implementation of control systems in place which ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of five establishments was selected from 12 establishments certified to export to the United States. During the establishment visits, the FSIS auditors examined the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. The FSIS auditors also focused on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems as outlined in Title 9 of the United States Code of Federal Regulations (9

CFR)§ 327.2, the FSIS regulation addressing the eligibility of foreign countries for importation of products into the United States.

Additionally, one private (network) laboratory's microbiological testing program and one government laboratory's residue program were audited to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	CCA- The National Service of Animal Health and Agro-Food Quality (SENASA), Buenos Aires
	Regional office	1	Regional Office, Santa Fe
Laboratories		2	Private - Microbiological Laboratory – Santa Fe Government - Chemical Residue Laboratory, Martinez, Buenos Aires
Meat slaughter and processing establishments		5	Est. 13, JBS Argentina, S.A., Villa Gobernador Gálvez Est. 1918, Ecocarnes, S.A., San Fernando Est. 1920, FCO Rioplatense, S.A.I.C.I.F., General Pacheco Est. 1970, Friar, S.A, Reconquista Est. 2025, FCO Gorina, S.A.I.C, La Plata

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

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

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

III. BACKGROUND

Currently, Argentina is eligible to export processed beef products to the United States. Argentina is a member of the World Organization of Animal Health (OIE) and is recognized as a country with a negligible risk regarding the prevalence of Bovine Spongiform Encephalopathy (BSE). In addition, the OIE declared Argentina free of Foot and Mouth Disease (FMD) with zones identified as free of FMD without animal being vaccinated and zones free of FMD where livestock is receiving vaccination.

USDA's Animal and Plant Health Inspection Service (APHIS), which regulates the importation of animals and animal products into the United States, has also recognized Argentina as having a negligible risk for BSE (9 CFR 92.5). Export of meat derived from head, cheek, weasand, or internal organs, and bone-in product will remain prohibited based on APHIS' animal health restrictions.

The region consisting of the areas of Patagonia South and Patagonia North B is recognized as free of Rinderpest and FMD by APHIS as specified in regulation 9 CFR 94.1 (a)(1) which lists the regions that APHIS has declared free of rinderpest and a list of regions APHIS has declared free of FMD disease. Importation of certain commodities from the northern region of Argentina to the United States is allowed if requirements specified in 9 CFR 94.29, in addition to other applicable requirements are met. 9 CFR 94.29 outlines the restrictions on importation of fresh (chilled or frozen) beef and ovine meat from specified regions listed in regulation 9 CFR 94.1 (a) (1).

The FSIS letter to SENASA dated September 27, 2016, stated that the audit would evaluate Argentina's system of controls for the production of intact beef intended for non-intact use, beef trim, and ground beef. In addition, the audit would examine controls to address Specified Risk Material (SRM) in cattle of all ages in accordance with regulations, decrees and circulars issued by the government.

From June 1, 2013 to May 31, 2016, FSIS import inspectors performed 100 percent re-inspection on 3,750,927 pounds of processed beef products exported by Argentina to the United States. FSIS also performed re-inspection on 3,344,087 pounds at POE for additional types of inspection (TOI), of which a total of 54,888 pounds were rejected; however, no product was rejected due to public health concerns.

The FSIS final audit reports for Argentina's food safety system are available on the FSIS Web site at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. The national government of the foreign country must design and administer an inspection system with standards equivalent to those of 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 onsite audit included record reviews, interviews, and observations made by the FSIS auditors. The audited facilities included government offices, one residue and one microbiological laboratory, and examination of five establishments certified to export to the United States.

FSIS verified that the Ministry of Agriculture, Livestock, and Fishery oversees SENASA and that SENASA is recognized as the CCA. SENASA manages Argentina's meat inspection system. Section 3 of Executive Decree No. 4238/1968**,** delegates the legal authority to SENASA to regulate and inspect products of animal origin and their by-products. SENASA is headed by a president who is supported by a vice president. The Presidency Unit (PU) of SENASA has three major components: General Management, National Directorates, and Office of Coordination. Other offices that directly report to the PU include Administrative Investigations, Advisory Council, Directorate for Regional Centers, Directorate for Legal Affairs, and Internal Audit Unit. Within PU there are five National Directorates and one General Directorate for Laboratories and Technical Control. These include National Directorate for Animal Health, National Directorate for Plant Protection, National Directorate for Agri-Food Safety and Quality, National Directorate for Technical and Administrative Issues, and National Directorate for Agrochemicals, Veterinary Products and Feed.

Although all national directorates and their sub-offices contribute to food safety assurance, it is mainly the National Directorate for Agri-Food Safety and Quality and its sub-directorate "Directorate for the Safety of Products of Animal Origin" that carry out the delivery of oversight at the establishments certified to export to the United States. Key tasks such as issuance of regulations, drafting national provisions, policies, procedures, and management of the official control and the delivery of training to the inspection staff occur at the central level.

In 2016, the CCA issued the following new circulars:

- Circular No. 4243/2016, New Requirements to Export Chilled and/or Frozen Raw Meat Derived From Bovine Carcasses Intended For the U.S.; and
- Circular No. 4246/2016, Procedure Manual for the Control Program of Shiga toxin-producing *Escherichia coli* O157:H7, O26, O45, O103, O111, O121, and O145 in Raw Beef.

Circular No. 4243/2016 directs the establishments that intend to export chilled and/or frozen raw beef products to the United States on the new requirements that must be met to be eligible for exporting such products. Circular No. 4246/2016 sets the requirements for establishments subject to the provisions in Executive Decree No. 4238/1968 to adopt sampling plans for the monitoring of Shiga toxin producing *Escherichia coli* (STECs) O157:H7, O26, O45, O103, O111, O121 and O145. The FSIS auditors verified the CCA's implementation of the Circulars was being performed as written.

The FSIS auditors interviewed the inspection personnel assigned to the audited establishments and verified the implementation of the requirements in Chapter II, (2.1.1) and (2.2.27) of Executive Decree No. 4238/1968, which requires that the CCA maintain a single standard of laws and regulations applicable to all establishments certified to export to the United States. In each of these establishments, the government officials assigned to the relevant regional office are responsible for the implementation of the official controls.

Regarding the funding of the meat inspection system, the FSIS auditors verified that nothing changed in the way that SENASA receives its operational funds since the last FSIS audit in 2014. The meat inspection program is funded from the national treasury according to the Act 25.164. The CCA disburses payment to each inspection program employee by directly

depositing salaries from appropriated funds in his or her personal bank account. Each employee also receives an earnings receipt issued by the CCA.

Ultimate control of establishments certified to export to the United States is achieved through the regional level. The coordination between the CCA and the regions occurs through the General Coordination Office for Regional Management, an entity under General Management within PU. Fourteen regional offices are responsible for the implementation of the official controls in the establishments certified to export to the United States. The current audit covered one regional office located in Santa Fe. The FSIS auditors verified that at the establishments certified to export to the United States located in these regions, the officials from regional coordination offices conduct inspection activities and enforce the United States import requirements.

The structure of SENASA also includes local offices or Veterinary Inspection Service (VIS). Each regional office is supported by four thematic coordinators who are responsible for carrying out official controls. Each slaughter and processing establishment certified to export to the United States is directly overseen by a head official veterinarian (OV), who is supported by a team of veterinary assistants (auxiliaries) in the VIS. The head OV reports to the public health regional level. The FSIS auditors verified that the staffing requirements outlined in Executive Decree No. 4238/1968, Chapter VIII (8.1.1) are being implemented in the audited establishments.

During the audit of the Santa Fe regional office, the government official gave a presentation regarding a variety of topics including recruitment of inspection officials, flow of information between the CCA's headquarters, regions and local inspection offices, and dissemination of FSIS requirements. The FSIS auditors interviewed officials and reviewed documents pertaining to management controls at the regional and local levels. Reviews of recruitment practices confirmed that the hiring follows the rules and guidance provided in Executive Decree No. 993/1991 "National System of the Civil Service" and Resolution No. 299/1995. The FSIS auditors examined performance evaluations of inspectors, which showed they are conducted once a year for each employee as required under the terms of Executive Decree No. 993/1991.

The CCA's headquarters staff performs initial and ongoing certification of establishments to export to the United States. Chapter XXX of Executive Decree No. 4238/1968 describes the regulatory requirements for sanitation, and Circular No. 3343/1998 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 produce products intended to 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 Executive Decree No. 4238/1968.

The FSIS auditors interviewed the CCA officials at headquarters and requested records related to implementation of corrective actions as applicable to the FSIS 2014 audit findings. Section 3 of Resolution No. 38/2012 delegates the CCA with the authority to require corrective actions in the establishments certified to export to the United States and to take additional enforcement measures as appropriate in accordance with Executive Decree No. 4238/1968. The FSIS

auditors confirmed that the CCA had verified the implementation and effectiveness of the corrective actions.

The CCA provides training to its inspection personnel in accordance with Chapter VIII of Executive Decree No. 4238/1968. The CCA maintains a copy of all the training records and certificates. During the audit of CCA's headquarters, the Santa Fe regional office, and microbiological and chemical residue laboratories visited, the FSIS auditors reviewed a sample of the training records and certificates and determined trainings are delivered in an ongoing and as needed basis.

At each audited establishment the FSIS auditors verified that per Circular No. 3958/2011, "Traceability and Recall (Commodities Recovery)" the food manufacturing establishments developed and implemented a traceability and recall (commodities recovery) program. Rules pertaining to this requirement for products or by-products of animal origin are prescribed in Chapter XXXI, Section 31.1.7, of Executive Decree No. 4238/1968, which mandates that establishments must develop traceability and recall procedures for their products. Inspectors are required to verify the efficacy of the program on a daily basis and must document the outcome of their assessment in appropriate records.

To verify efficacy, inspectors randomly select at least one batch of records for review. The inspectors verify that the records contain the date of reception, type of products or materials received, weight, certificate number, destination, and assigned number of batch of entry. At slaughter establishments, these records must also include identifications that allow the individual carcasses to be traced back to the herds.

The FSIS auditors also verified that the CCA has the legal authority and responsibility to approve or disapprove laboratories conducting analytical testing of products to export to the United States. The National Directorate for Technical and Administrative Issues (DILAB) and its sub-offices within SENASA provide technical laboratory support for microbiological and chemical residue testing programs. The responsibilities and functions of DILAB include:

- Establishing the official methods and protocols of analysis;
- Certifying through analytical testing of the products controlled by SENASA;
- Managing and controlling the National Network of Laboratories (NNL);
- Assisting other SENASA Directorates;
- Complying with quality standards and procedures;
- Complying with biosecurity standards established by SENASA; and
- Providing training, education, and advanced skills to analysts.

A complex of more than 400 laboratories comprises the NNL. The participating laboratories are required to register with SENASA under the provisions of Article 1 of Resolution No. 736/2006. In addition to providing technical support to the NNL and DILAB, officials of regional laboratories conduct audits of the NNL, focusing on the quality management system (QMS) and record keeping as required under the provisions of Resolution No. 138/2002. Whether a laboratory in the NNL conducts official tests for the CCA or for an establishment determines its type as an "authorized" or a "recognized" laboratory. These classifications of NNL laboratories have been stipulated in Articles 3 and 5 of Resolution No. 138/2002. The NNL chain includes

provincial institutions or private laboratories and only authorized laboratories are permitted to conduct testing on official samples for government verification, including products destined for export to the United States. During a visit to the government laboratory the auditors reviewed a sample of documents regarding the registration and QMS reviews of a private laboratory entering into the NNL system. The FSIS auditors concluded that the NNL process follows the provisions of Resolution No. 736/2006.

The use of a network laboratory to conduct analysis on official samples collected by government inspectors was identified as a concern in the 2014 FSIS audit. In September 2015, SENASA requested an individual sanitary measure equivalence determination, which is currently pending with FSIS. The CCA continues to organize and administer its meat inspection system in a manner that meets the core requirements for this component.

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

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

At each audited slaughter establishment, the FSIS auditors interviewed inspection staff responsible for the implementation of the Animal Welfare and Humane Slaughter (AW-HS) program and reviewed documents generated by the establishment as well as verification records maintained by the inspectors. The FSIS auditors also visited pens, ramps, and drive ways; observed stunning of cattle; and determined that the slaughter establishments are complying with SENASA's requirements for AW-HS.

The FSIS auditors verified that the cattle brought to slaughter are receiving ante-mortem examination in accordance with the requirements specified in Chapter X of Executive Decree No. 4238/1968. The FSIS auditors observed that arriving batches (referred to as troops) of animals for slaughter are accompanied with shipment documents including sanitary certificates about the herd. These documents are verified by the ante-mortem veterinarian or designee for the accuracy and traceability of the herd prior to conducting ante-mortem examination. Each health certificate covers the animals in one troop, which can be broken down into smaller lots while maintaining the identity of the troop. The FSIS auditors reviewed a sample of the shipping documents and determined that activities were conducted in accordance with Rule 10.15 of Executive Decree No. 4238/1968.

Arriving animals are allowed to rest prior to slaughter and have free access to water, and if the resting period extends over 24 hours the animals have free access to food. Ante-mortem

inspection of cattle presented for slaughter is conducted in designated areas of the establishment's premises in accordance with the procedures outlined in Rule 10.1.15 of Executive Decree No. 4238/1968.

The inspection of livestock procedures requires examination of cattle on both sides while they are moving in the pen. The results of examination of cattle in each pen are documented on a pen card. All cattle suspected of exhibiting signs of illnesses including central nervous system or metabolic disorders, disabling injuries or contagious diseases are retained for further evaluation before being declared unfit for slaughter or released for slaughter.

The FSIS auditors interviewed the ante-mortem inspectors and determined that they are trained to detect and handle animals suspected of having FMD. Rule 10.3 of Executive Decree No. 4238/1968 laid out the principal control measures in the event animals suspected of having FMD are identified during ante- mortem inspection. It is the establishment's responsibility to inform VIS if the load of consignment for slaughter contains dead or dying animals. Animals that are suspected of having died from infectious or contagious diseases are sent for necropsy prior to condemnation in accordance with Rule 10.4 of Executive Decree No. 4238/1968.

SENASA has developed the following manuals:

- Manual of Procedures for the Veterinary Inspection of Red Meat Establishments;
- Manual of Procedures for the Assistant Veterinaries at the Beef Kill Floor; and
- Manual of Procedures for Control at Beef Kill Floor.

These manuals, together with other documents, are intended to facilitate unified application of regulations to ensure consumer health and protect animal health. Manuals also serve as guidelines by establishments to achieve compliance with government regulations.

To verify the procedures Argentina employed to conduct post-mortem inspection, the FSIS auditors reviewed the manuals and conducted interviews with the inspectors and reviewed documents pertaining to the implementation of government regulations, resolutions, decrees, and circulars on identification, elimination, and disposition of SRM and pathological lesions, including FMD lesions. The FSIS auditors verified the CCA's implementation of the Decree and Manuals being performed as written.

The FSIS auditors verified that SENASA requires all beef slaughtering plants to develop and implement SRM removal programs in accordance with Circular No. 4212/2015. Through interviews, document reviews and onsite observation of procedures for SRM removal, the FSIS auditors concluded that the brain, cerebellum, and spinal cord were being removed. The auditors observed that inspectors were verifying the establishment's procedures for SRM per the instructions outlined in Circular No. 4212/2015.

While verifying SRM removal procedures at the kill floor, the FSIS auditors noted:

- The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions, which could lead to product contamination. This finding was also noted during the FSIS audit conducted in 2012.

The FSIS auditors noted that under the supervision of official veterinarians, veterinary assistants performed the inspection of the feet, lips, and muzzles of each slaughtered animal to detect the presence of FMD lesions. FMD lesions trigger a series of actions involving reporting to National Directorate for Animal Health. A review of records indicated no findings of FMD.

The FSIS auditors verified the CCA's controls over condemned materials. The definition, isolation, and disposal of slaughter or processing wastes are provided in Circular No. 3528/2003. Slaughter and processing establishments waste are categorized into slaughter waste free of SRM, slaughter waste containing SRM, and processing waste with or without SRM. For management and disposal of each type of waste, the circular provides distinct requirements with which establishments must comply, and are verified by inspectors either through observation, record review, or both. The FSIS auditors reviewed inspection verification records concerning the disposition of the condemned products. The verification of these requirements did not raise any concern in audited establishments. However, one establishment was delisted during the audit by SENASA for insanitary conditions observed, including SRM waste from the beef carcasses falling into regular inedible waste containers placed adjacent to SRM waste containers, as observed by the FSIS auditors during the audit.

Chapter II (2.1.1) of Executive Decree No. 4238/1968, provides the legal authority for the CCA's oversight controls over each establishment's construction, facilities, and equipment. The FSIS auditors verified that the audited establishments are complying with the provisions of this document while the inspection personnel enforce the applicable requirements.

The FSIS auditors verified that each establishment certified to export to the United States receives periodic supervisory visits from the regional level. Interviews were conducted at the regional directorate office and local veterinary offices. Reviews of supervisory reports at the offices indicate that the frequency of the reviews adheres to instructions provided in Circular No. 4056/A. In slaughter establishments, regional supervisors perform reviews monthly, or more often if warranted. Supervision in processing establishments or cold storage facilities is maintained at a bimonthly frequency. The regional supervisory control procedure includes the evaluation of the inspectors as well as establishments. At each audited establishment the FSIS auditors selected a sample consisting of the last three supervisory reviews and determined that the reviews were conducted in accordance with the procedure manual referenced in Resolution No. 505/1998. A copy of the completed signed report is also provided to the establishment's management; usually to the head of the quality control group, who signs all copies of the report. In addition to periodic supervisory reviews, the local inspection offices are also reviewed at least once a year at the central level. The review also includes an evaluation of the local OV's performance. The FSIS auditors did not identify any concern as result of the review of supervisory reports.

Argentina's meat inspection system continues to maintain the legal authority and a regulatory framework to implement requirements equivalent to those governing meat inspection in the United States, although some weaknesses were identified regarding oversight related to post-mortem inspection procedures.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit.

In all five audited establishments, the FSIS auditors verified that SENASA exercises its legal authority to require all establishments certified to export to the United States to develop and maintain sanitation programs to prevent direct product contamination and creation of insanitary conditions.

SENASA issued a series of decrees and circulars to achieve establishment compliance with the sanitation requirements consistent with the United States regulatory requirements codified in 9 CFR 416. The verification of this component consisted of interviews with the veterinary inspection staff at each audited establishment; document reviews of each establishment's sanitation and inspector's verification records; and onsite observation of each establishment's operational sanitation and preoperational sanitation procedures.

The FSIS auditors verified that the design and implementation of sanitation programs at each establishment was in accordance with the following decrees and circulars pertinent to this component:

- Executive Decree No. 4238/1968, Regulations for the Inspection of Products of Animal Origin, By-Products, and Derivatives with Chapter II on Good Manufacturing Practices, Chapter III on Sanitary Building and Engineering of Slaughter Establishment, and Chapter XXXI on Standard Operating Procedures;
- Circular No. 3271/1997, Implementation Of Sanitation Standard Operating Procedures By The Establishments;
- Circular No. 3837/2008, Supplement to Circular No. 3271/1997 - Company SSOP Implementation Procedure and Verification by the Veterinary Inspection Service; and
- Circular No. 3297/1997, Guidelines for SSOP Evaluation and Verification Focusing on Evaluation and verification of Pre-Operational and Operational Aspects of Sanitation.

Circular No. 3837/2008 supplements Circular No. 3271/1997 for SSOP procedures implemented by the establishments certified to export to the United States. The Circular No. 3837/2008 also contains instructions for VIS to be employed while verifying the establishment's SSOP. In addition to the requirements for general sanitation in these government issuances, SENASA issued Circular No. 3418/2000 which sets forth the procedure and guidance to be followed in case of positive results for *Listeria monocytogenes* (*Lm*) in cooked products and products intended either for the domestic market or export. VIS routinely verifies the compliance of Circular No. 3418/2000 in conjunction with verification of the establishment's SSOP, HACCP system, and prerequisite programs. In case a noncompliance is found during routine verification, an appropriate enforcement action is taken, which may range from the tagging of rooms or equipment to the condemnation of implicated products.

Inadequate implementation of sanitation controls were observed in four of the five establishments certified to export to the United States. SENASA delisted one of the five audited establishments due to multiple insanitary conditions observed throughout the facility. These insanitary conditions could potentially lead to the contamination or adulteration of products. The CCA committed not to relist the establishment until SENASA verified the corrective actions associated with the delisted establishment. The verification of this component did not raise any significant issues, except for the delisted establishment, the sanitation issues did not appear to pose direct product contamination.

At the audit exit meeting, the CCA provided the FSIS auditors with evidence that the delisted establishment's sanitation non-compliances had been corrected. FSIS' ongoing assessment of Argentina's meat inspection system indicated that it maintains clearly defined requirements and controls. The observations made in each establishment pertaining to the Government Sanitation component were noted and detailed in the individual establishment checklists in Appendix A of this report.

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

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

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations made during the onsite audit. The CCA's headquarters, one regional directorate, and five establishments were audited to verify whether the CCA maintains effective government oversight for the implementation of Argentina's beef inspection system and, in particular, the HACCP requirements.

The review of CCA's issued documents pertinent to HACCP requirements indicates that the CCA requires each establishment to conduct a hazard analysis and control hazards identified as likely to occur with a CCP. For the hazards identified as not likely to occur, establishments must have support for these decisions.

As outlined in Circular No. 4008/2012, *E. coli* O157:H7 and other Shiga toxin producing serogroups including O26, O45, 0103, O111, O121 and O145 are biological hazards, and product is declared adulterated if it tested positive for the presence of *E. coli* O157:H7 or other STECs. This circular requires the establishment to reassess its HACCP plan in the event that either the establishment's or the CCA's test results reveal product contamination with any of these adulterants. The FSIS auditors verified the CCA's implementation of this Circular was being performed as written.

The FSIS auditors verified that each establishment has identified the presence of *E. coli* O157:H7 or other STECs pathogens as a biological hazard and addressed it through validated

controls which include pre- and post- slaughter interventions applied throughout the operation. The FSIS auditors observed that arriving cattle are constantly sprayed with water prior to reaching the kill floor. Each step at the kill floor has specific controls to prevent carcasses from getting contaminated. Validated organic acid sprays with time/temperature are applied with defined pressure to the entire carcass before it enters the chilling rooms. Establishments verify the efficacy of these controls through routine testing for *E. coli* O157:H7 and other STECs. The VIS samples the product for *E. coli* O157:H7 and verifies the establishment testing results for other STECS. No concerns arose as a result of the audit verification activity.

STEC controls are outlined in Circulars No. 4210/2015 and No. 4210A/2015. In Annex VIII of Circular No. 4210/2015, SENASA defines the High Event Period (HEP) and requires establishments slaughtering cattle to consider all the parameters associated with their production and establish HEP accordingly. The FSIS auditors verified the CCA's implementation of these Circulars was being performed as written.

At the five audited establishments, the FSIS auditors verified through record reviews and observations that the in-plant inspection personnel conducted daily verification of HACCP plans in accordance with the methodology described in the procedural manuals issued by SENASA.

The FSIS auditors reviewed zero tolerance (e.g., feces, ingesta, and milk) Critical Control Point (CCP) records and noted that the all slaughter establishments conduct monitoring in accordance with their written HACCP plans. The FSIS auditors also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. The relevant section of Resolution No. 38/2012 authorizes inspection to require corrective action, when there is a deviation or failure, which may range from retaining equipment, rejecting noncompliant product, or suspending the establishment's eligibility to export.

Through a records review, the FSIS auditors verified that each audited slaughter establishment addresses fecal/ingesta and milk contamination as a CCP in the HACCP plan and establishes Critical Limit (CL) as a zero tolerance. The FSIS auditors also verified at all slaughter establishments that in-plant daily inspection verification included CCP verification with results entered in the inspection records. The FSIS auditors reviewed the last 90 days' of records pertaining to the CCP for zero tolerance and observed that the audited slaughter establishments were monitoring the CCP and taking corrective actions as specified in the plan.

The FSIS auditors verified that each cattle slaughter establishment implemented controls for BSE during ante-mortem examination and takes SRM into consideration when conducting hazard analysis. Since Argentina has acquired a "Negligible Risk" status by OIE and subsequently by APHIS, cattle presented for slaughter are not segregated as over thirty months or under thirty months but treated as being in the same age group.

In order to control known pathogens (e.g., *Listeria*, *Salmonella*, and *E. coli* O157:H7*)* in Ready-to-Eat (RTE) meats derived from bovine species, the CCA issued Circular No. 3555/2003 and other circulars referenced in the relevant sections of the report. The requirements of this circular for the establishments processing RTE products exposed to the post-lethality production environment are consistent with the United States regulatory requirements as specified in 9 CFR

430. The FSIS auditors verified the CCA's implementation of this Circular were being performed as written.

The government-employed inspectors in VIS conducted procedures designed to verify the daily HACCP monitoring and verification activities in all establishments certified to export to the United States. The inspection staff can refer to Circular No. 3390/1999 and Circular No. 3485/2002 for instructions on verification and evaluation of an establishment's HACCP plans. SENASA has documented and administered a food safety program equivalent to HACCP in the United States. The FSIS auditors verified the CCA's implementation of these Circulars was being performed as written. Except as noted below, no other issues were identified as a result of verification of this component.

- In one audited establishment, the review of the written HACCP plan demonstrated that the critical limit for controlling *Clostridium perfringens* did not include a procedure to monitor the temperature of the product; it only included a timeframe. The Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) (Appendix B) was utilized as support for the critical limit. Appendix B outlines the need for a time and temperature relationship to control the outgrowth of Clostridium spores.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

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

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed Argentina's 2016 residue sampling plan, associated methods of analysis, and additional SRT responses outlining the structure of Argentina's chemical testing program. It was also noted that there have not been any POE violations related to this component since the last FSIS audit.

Although there have not been any POE violations for ivermectin since the last reported violation in 2011, SENASA issued Circular No. 4244 /2016. This circular established new maximum allowable level to coincide with those established by the Food and Drug Administration (FDA).

This circular repeals all previous circulars on ivermectin control. The following circulars were repealed effective October 31, 2016: Circulars No. 3980/2011, 3980A/2012, and 3980B/2015. The authorized beef slaughtering establishments subjected to the provisions of the circular are required to test product (muscle) of each shipment destined for the United States, and should inform VIS of any result that does not comply with the maximum levels indicated above.

The FSIS auditors verified that the CCA has a "Plan for Control of Residues and Hygiene in Food Products of Animal Origin" (CREHA). CREHA is organized and administered by the national government, and includes random sampling of internal organs, muscle and fat of carcasses for chemical residues. The plan establishes priorities not only related to chemical residues and

additives, but also related to toxins and microorganisms and select entities in each group of chemicals that pose the greatest risk to public health. Random sampling of chemical species utilizes the guidance provided in Codex document titled "CAC/GL 71/2009 - Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programs Associated with the Use of Veterinary Drugs in Food Producing Animals" as a statistical basis for the number of samples to be analyzed in the plan.

The main objective of directed sampling is to target a chemical entity, product, or establishment as warranted. Frequencies of directed sampling are risk-based; thus, chemicals posing higher risk to public health or a product consumed at higher rate or an establishment with a proportionately higher number of positive results will be targeted more frequently.

All testing mandated by CREHA is conducted at the government laboratories or at laboratories registered in the NNL. In all audited establishments, the FSIS auditors verified that inspectors receive testing schedules for their respective plants with shipping material and documents. The FSIS auditors verified that the inspection personnel were following the 2016 residue sampling plan as intended in all five audited establishments.

The FSIS auditors visited the General Directorate of Laboratories and Technical Control - DILAB reference laboratory located in Martinez, Buenos Aires and audited the chemical residue testing program. This laboratory is ISO (International Standardization Organization) 17025 accredited by Organismo Argentino de Acreditación (OAA) in the specific areas of testing. The FSIS auditors reviewed the most recent accreditation audit report of the laboratory that took place in March 2015. The OAA accreditation review identified minor issues, which the laboratory remedied and provided corrective actions to OAA.

The FSIS auditors interviewed the analysts to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The document review also included an evaluation of management system documents; 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. The review of intra-lab and inter-lab evaluations administered by the laboratory supervisor indicated that the analysts possessed the competencies necessary to conduct the analysis assigned to them. The FSIS auditors further observed that the laboratory personnel at the sample receipt area were receiving samples; checking sample integrity and security; assigning the identification; and storing the samples in accordance with the laboratory's standard operating procedures. No concerns arose as a result of the laboratory audit.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced to export to the United States are safe and wholesome. The evaluation of this component included an analysis of information provided by the CCA in the SRT, with interviews and observations made during the onsite equivalence verification audit.

The FSIS auditors verified that SENASA required all slaughter establishments certified to export to the United States to implement testing programs for indicators of fecal contamination to assess slaughter and sanitary dressing procedures. The testing program described in Circular No. 3834/2006 is consistent with United States regulatory requirements (9 CFR 310.25) in official slaughter establishments. The FSIS auditors reviewed the written generic *E. coli* program and the records of analytical testing results produced by the establishments for the previous 90 days. The FSIS auditors also observed the establishment's quality control program employees collecting the samples from chilled beef carcasses using the aseptic sampling techniques at slaughter/processing establishments. No concerns arose as a result of the audit verification activity

The CCA has developed a *Salmonella* testing program for chilled livestock carcasses as described in Circular No. 3764/2007, titled "*Salmonella* Testing for USA." The performance standards described in the document are consistent with the provisions specified in 9 CFR 310.25. The Annex 1 of this circular provides instructions on measures to be taken when establishments do not meet the standards. For instance, in the event that an establishment fails the first set, Annex I requires immediate corrective action followed by a second set of samples collected by the CCA. *Salmonella* samples are collected by government inspectors and analyzed in the NNL. The FSIS Microbiology Laboratory Guide (MLG) 4.04 method was adopted and is used for carcass sponging for *Salmonella* testing.

In order to determine whether the inspection system provides for a sampling and testing program for *E. coli* O157:H7 and six additional non-O157 STECs (O26, O45, O103, O111, O121, and O145) in beef products intended to be used for non-intact products and beef manufacturing trimmings, the FSIS auditors evaluated the following circulars:

- Circular No. 3834/2006, Prevention and Control of *E. coli* O157:H7*;*
- Circular No. 4008/2012, USDA/FSIS Requirements for Verification of Shiga Toxin Producers In Addition to *E. coli* O157:H7;
- Circular No. 4023/2012, *E. coli* O157:H7 Testing Controls for *Listeria monocytogenes* in RTE Products (For FSIS-USDA);
- Circular No. 4210A/2015, Official Sample Collection Activities for Verification of Contamination by Escherichia coli (STEC) and Salmonella in Raw Beef; and
- Circular No. 4246/2016, on Procedure Manual for the Control Program of Shiga Toxin-producing *Escherichia coli* O157:H7, O26, O45, O103, O111, O121 and O145 in raw beef.

In Circular No. 3834/2006, one important feature pertinent to sampling for *E. coli* O157:H7 is that the sample must be collected from trimmings and bench trims, and if no trimming is available due to the characteristics of the establishment's process, samples should be collected from primal cuts or quarters. In Circular No. 4008/2012, all establishments certified to export to the United States are required to reassess their HACCP plans when testing identifies a positive result for either *E. coli* O157:H7, or for any Shiga toxin-producing serogroups (O26, O45, 0103, O111, O121 and O145). According to Circular No. 4008/2012, the presence of any STEC in non-intact raw products or other raw ground beef components renders the product adulterated. As such, the result of the analysis should be considered "non-acceptable" if the result is positive for any of these serotypes, including *E. coli* O157:H7.

The official sampling plan described in Annex I of Circular No. 4210/2015 exempts intact cuts from *E. coli* non-O157:H7 STEC sampling. Official sampling covers all products intended to be used in raw non-intact products (e.g., ground beef, hamburgers, etc.) or when the intended use of intact product is not clearly defined. Annex VII assigns responsibility to inspectors to verify the establishment's (manufacturing raw beef products) compliance with regulatory requirements through the assessment of HACCP plans when the product tested positive for STEC. Annex VIII deals with trace back procedures when samples test positive and requires establishments to identify HEP for their processes.

All beef slaughter and processing establishments operating under Executive Decree No. 4238/1968 that intend to produce and export raw beef product to the United States are required to develop and implement testing programs as outlined in Circular No. 4246/2016. The circular highlights the following sampling characteristics:

- Lot determination: each authorized establishment defines its production lots that must be communicated to the inspector in charge initially and whenever a change occurs. Circular No. 4246/2016 prohibits a lot to be defined from sanitation to sanitation interval. It is suggested that the maximum capacity of the production batch defined by the establishment should not exceed 700 boxes of raw bovine meat making it convenient for shipment and recall of any United States consignments if necessary. The production batch must also have the following characteristics:
    - Represent a defined production unit, clearly identified, accessible and easy to inspect;
    - Be produced within a certain time interval, in the same production line without interruptions of the flow; and
    - Must be traceable.
- Official sampling includes non-intact product intended for minced meat, hamburgers, etc. As indicated above, no official samples for intact cuts (anatomical) or for raw meat cuts intended for the production of RTE products. Production lots pending test results either from the establishment's own testing or official testing will be retained until negative results are obtained;
- The design of the sampling procedure for N60 must consider procedures as described in FSIS Directive 10,010.1 (current Rev.); Sampling Verification Activities for Shiga Toxin-Producing *Escherichia. coli* (STEC) in Raw Beef Products;
- Analyses conducted at DILAB, network or private laboratory for samples from either establishment's own testing or from official testing must be reported to a supervisor if tested positive. A positive sample may trigger corrective action and follow-up sampling.

SENASA published Circular No. 3555/2003 and Circular No. 3961/2011 titled "Control of *Listeria moncytogenes* in RTE Products Exported to the United States" and "Equivalence Criteria Control Program for *Listeria monocytogenes* in Ready-to-Eat Product," respectively. These documents require that all establishments manufacturing meat and poultry 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 *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, SSOP, or other prerequisite programs to prevent product adulteration by *Lm*. The network

of government approved laboratories is using MLG 8.09 method for detection of *Lm* and MLG 4.08 method for detection of *Salmonella* in RTE meat. The Circular No. 4023/2012 provides Sampling guideline for RTE products based on production volume.

Lastly, in order to determine if the CCA has adequate administrative and technical support to operate the inspection system, among other verification activities, the FSIS auditors also included a review of a network participating microbiological laboratory "Merco Lab" in the scope of the audit. The laboratory is located in Santa Fe and currently conducts *Salmonella* testing for the establishments certified to export to the United States in the region.

The FSIS auditors reviewed the recent ISO 17025 accreditation report issued by OAA. The laboratory has corrected the concerns identified by OAA and presented corrective actions, which OAA accepted. The FSIS auditors interviewed analysts and reviewed their training records. The review determined that all analysts received required training to conduct analytical testing. The FSIS auditors verified the CCA's implementation of the microbiological testing programs was being performed as written. No concerns were identified as a result of the laboratory audit.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 13, 2016, in Buenos Aires with SENASA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The CCA understood and accepted the findings.

The current audit did not identify any concerns that represented an immediate threat to public health. During the audit exit meeting, the CCA committed to begin to address the preliminary systemic and isolated findings as presented and provided additional evidence that many of the isolated findings related to SRM removal procedures, sanitation, and HACCP described on the individual establishment checklists (Appendix A) had been addressed.

The FSIS auditors identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS

- The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions, which could lead to product contamination. This finding was also noted during the FSIS audit conducted in 2012.

GOVERNMENT SANITATION

- In four of five audited establishments, the FSIS auditors observed findings related to requirements of SPS. SPS findings are noted in the respective establishment checklists provided in Appendix A of this report. SENASA delisted one of the audited establishments that posed a potential for product contamination.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- In one establishment, the HACCP plan's critical limit was not supported. A review of the written HACCP plan demonstrated the critical limit for controlling *Clostridium perfringens*

did not include a procedure to monitor the temperature of the product; it only included a timeframe. The Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) (Appendix B) was utilized as support for the critical limit. Appendix B outlines the need for a time and temperature relationship to control the outgrowth of Clostridium spores.

FSIS expects that the CCA will implement prompt corrective actions to address the above reported finding and provide to FSIS a report on the adequacy of their implementation within the next 60 calendar days. FSIS will further assess the equivalence of Argentina's meat inspection system upon receiving the CCA's proposed corrective actions for the reported findings.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
JBS Villa Gobernador Gálvez Santa Fe	11/30/2016	13	Argentina
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance 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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

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

39/51 Broken tiles, exposed concrete were observed multiple production rooms.
46/51 Dirt or debris collected behind doors to the production rooms and in the spaces at the wall floor junctions. This condition was very notable at one electrical junction box in close proximity to chilling room. No direct product adulteration was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/30/2016

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
ECOCARNES San Fernando, Buenos Aires	12/06/2016	1918	Argentina
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance 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 .	X
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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Specified Risk Material (SRM) Controls	X
59.	

60. Observation of the Establishment

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

14/46/51 At the spinal cord removal station the plant was not following the written pre-requisite program for the removal of SRM materials, which requires disposal of SRM material into a digester and the use of a black handled knife for removal. The auditors noted that the plant personnel were not using black handled knives while removing spinal removal station. The auditors further noted that, the SRM were being collected both at the digester and in general waste material.

38/46/51 While touring the outside of the facility bloody pooled water, moldy walls and product residues were observed on the grounds and around offal shipping area. Flies were observed around shipping docks and hovering over the pool of standing water near shipping docks.

39/46/51 In the boning and packing area the following was observed:

- Moldings around some areas of ceilings were broken and hanging above exposed products.
- Numerous insulated pipes were broken to the extent that insulation was readily protruding out of the coverings.
- Peeling paint, broken flooring was observed in multiple production areas.
- Dirt and residue buildup around food processing equipment, freezers, carcass coolers and in multiple production rooms was observed.
- At the boning room entrance and the surrounding areas dirt and mold were observed on the ceilings and walls. Dirt collected on parts of ceiling that was directly over the moving carcass quarter rails.

41/46/51Beaded condensation was observed in the boning area on the rails and beams above exposed carcass quarters.

58/51 The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions which could lead to product contamination.

The SENASA officials Delisted the establishment and withdrew its eligibility to export to the United States.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/06/2016

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
Frigorífico Rioplatense General Pacheco, Buenos Aires	12/05/2016	1920	Argentina
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance 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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Specified Risk Material (SRM)	X
59.	

60. Observation of the Establishment

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

39/51 Broken floors or exposed concrete permitting water, waste and organic collection in more than one production rooms

45/51 In boning room rough welds and holes were observed on food contact surfaces that were made up of stainless steel.

46/51 Rust and dirt collected on segments of overhead rails, loose electrical cables in the processing room.

Two sterilizers used by employees of boning room to sterilize knife had stagnant water with residue buildup.

58/51 The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions which could lead to product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/05/2016

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
F.R.I.A.R Reconquista, Santa Fe	12/01/2016	1970	Argentina
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/01/2016

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
Frigorifico Gorina SAIC, La Plata Buenos Aires	12/12/2016	Est. 2025	Argentina
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

60. Observation of the Establishment

The following non-compliances were not identified by Argentina's inspection officials during the establishment review:
46/51 Water and meat waste was pooling in a processing room due to a clogged drain in the room.
58/51 The impact of the stunning device often results in extrusion of brain matter through the hole in the skull. Spillage may create insanitary conditions which could lead to product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/12/2016

Appendix B: Foreign Country Response to Draft Final Audit Report

Ministerio de Agroindustria
Servicio Nacional de Sanidad y Calidad Agroalimentaria
Coordinación de Relaciones Internacionales

NOTA CRI Nº 3168/ 2017

Para	**JANE H. DOHERTY**
Institución:	**INTERNATIONAL COORDINATION EXECUTIVE** **OFFICE OF INTERNATIONAL COORDINATION** **FSIS**
Email:	jane.doherty@fsis.usda.gov
De:	**MARÍA INÉS VICA**
Institución:	**SENASA**
Teléfono:	**4121-5353**
Fax:	**4121-5360**
Fecha:	**19 de julio de 2017**
e-mail:	relint@senasa.gov.ar
Total de páginas: ***(incluye la cubierta)***	**6 (seis)**

ESTADOS UNIDOS – Respuesta de SENASA al Borrador de Informe de la Auditoria in situ al Sistema de Inspección de Carne Argentino del 29 de noviembre al 13 de diciembre de 2016.-

Prioritario

Tengo el agrado de dirigirme a usted, a efectos de dar respuesta al borrador final emitido por el FSIS, en virtud de la auditoría realizada en nuestro país desde el 29 de noviembre hasta el 13 de diciembre del 2016, con el fin de evaluar los sistemas de seguridad alimentaria de los productos cárnicos exportados hacia los Estados Unidos de Norteamérica.

SENASA aprecia los esfuerzos del FSIS en la realización de la auditoría y agradece la oportunidad de poder comentar el Proyecto de Informe Final. Los comentarios para la apreciación por parte del FSIS son proporcionados en el **Anexo I,** que se adjunta.

Al respecto, de los hallazgos sobre tres de los seis componentes de equivalencia del sistema auditado, que no representan un riesgo inmediato para la Salud Pública y sobre los que el SENASA aportó pruebas durante la reunión final, se desarrolló una respuesta específica que se adjunta como **Anexo II**.

Atento a la documentación provista, consideramos que nuestro Sistema Nacional brinda las garantías equivalentes a la Normativa Americana, y esperamos pueda otorgarse la autorización para la exportación de carne cruda vacuna a los Estados Unidos de Norteamérica, a la mayor brevedad posible.

Sin otro particular, saludo muy cordialmente,

María Inés VICA
Coordinadora de Relaciones Internacionales
SENASA

Courtesy translation

This report was drawn up in response to the final draft issued by FSIS, in relation to the audit conducted in our country from November 29 to December 13, 2016, in order to assess the food safety systems for meat products exported to the United States of America.

SENASA appreciates FSIS efforts to carry out the audit and thanks for the opportunity to comment on the Draft of the Final Report. Comments for FSIS consideration are provided in **Annex I**

In this sense, in relation to the findings on three out of six equivalence components of the system audited, which do not pose an immediate risk for Public Health and for which SENASA provided evidence during the closing meeting, a specific response was developed in **Annex II**.

In view of the documents provided, we consider that our National Service provides equivalent assurances to the American Legislation, and we look forward to obtaining authorization to export raw beef to the United States of America.

ANNEX I: COMMENTS FOR FSIS CONSIDERATION

Section of report, page and paragraph of reference	Comment on the Report	CAA Response	CAA Request
Section IV, Page 4, Paragraph 3	1. During 2016, the CAA issued Circular Letters 4243/16 and 4246/16. 2. Circular Letter 4246/16: Procedural Manual for the Control Program of Shiga Toxin Producing *E. coli*, Types O157:H7, O26, O45, O103, O111, O121, and O145 in Raw Beef.	1. During 2016, the CAA issued Circular Letters 4243/16, 4246/16, 4244/16 (Ivermectin), and 4245/16 (*Salmonella*). 2. Clarification: the correct number of the Circular Letter is 4210A, Procedural Manual for the Control Program of Shiga Toxin Producing *E. coli*, Types O157:H7, O26, O45, O103, O111, O121, and O145 in Raw Beef.	1. Complete with missing Circular Letters. 2. Replace Circular Letter 4246 by Circular Letter 4210 A in the text.
Section IV, Page 5, Paragraph 4	Circular Letter 3343/98 refers to the regulatory requirements of HACCP, Standard Sanitation Operative Procedures (SSPO), Sanitary Performance Standards (SPS), requirements on humane handling and slaughter and analytic methods for generic E. coli.	This National Service is willing to clarify that non-compliance with what has been laid down in Circular Letter 3343/98 determines that eligibility to export to the U.S.A. be suspended by the CAA.	Amend paragraph.
Section V, Page 7 Paragraph 3	Reference is made to numeral 10.15 of Executive Decree 4238/68	The correct reference numeral of this topic is 10.1.5.	Replace numeral.
Section V, Page 8, Paragraph 6	FSIS auditors verified that SENASA requires all establishments of bovine slaughter to develop and implement programs to remove SRM in accordance with Circular Letter 4212/2015. By means of interviews, documentary checks, and on-the-spot observations of the procedures to eliminate SRM, FSIS auditors	The correct Circular Letter numeral is 3528/2003. Said Circular Letter includes the definition, isolation, and elimination of SRMs.	Replace Circular Letter 4212/2015 by Circular Letter 3528/2003.

	determined that brains, cerebellum and spinal cord were properly eliminated. The auditors noted that the inspectors verified the procedures for SRM of the establishments in accordance with the guidelines of Circular Letter 4212/2015.		
Section VI, Page 10, Paragraph 4	Decree No. 4238/68, Regulation for the Inspection of Products, By-Products and Derivatives, Chapter II on Good Manufacturing Practices.	The correct Chapter is XXXI which deals with the Good Manufacturing Practices.	Amend Chapter number.
Section VI, Page 10, Paragraph 5	VIS routinely verifies compliance with Circular Letter 3418/2000, SSOPs, HACCP system, and the prerequisite programs of the establishment.	Circular Letter 3418/2000 was repealed and replaced by Circular Letter 4063/2013.	Amend Circular Letter number.
Section VII, Page 12, Paragraph 2	STEC controls are described in Circular Letters 4210/15 and 4210 A/15.	Circular Letter 4210/15 was repealed and replaced by Circular Letter 4210 A/16.	Amend Circular Letter number.
Section VII, Page 12, last paragraph	To control known pathogens (for example, *Listeria*, *Salmonella*, *E. coli* O157:H7) in ready-to-eat meat (RTE) derived from the bovine species, the CAA issued Circular Letter 3555/2003 and other Circular Letters that are referred to in the relevant parts of this report.	The Circular Letters that would be suitable for this paragraph are 4066/2013 and 4066 A/2013. Circular Letter 3555/2003 only deals with microorganism *Listeria* for this type of product.	Amend Circular Letter number.
Section IX, Page 15, Paragraph 2	The CAA has developed a *Salmonella* control program for chilled livestock carcasses in accordance with the provisions of Circular Letter 3764/2007.	Circular Letter 3764/2007 has been repealed and replaced by Circular Letter 4245/2016.	Amend Circular Letter number.
Section IX, Page 15, Paragraph 3	Circular Letter 4023/2012, *E. coli* O157:H7: *Listeria monocytogenes* control testing in RTE products (for FSIS-USDA).	Circular Letter 4023/2012 was repealed and replaced by Circular Letters 4066/2013 and 4066 A/2013.	Amend Circular Letter number.
Section IX, Page 16, Paragraph 1	The official sampling plan which is described in Annex I to Circular Letter	Circular Letter 4210/2015 was repealed and replaced by Circular Letter 4210	Amend Circular Letter number.

	4210/2015 excludes intact cuts from undergoing sampling for non-O157:H7 *E. coli* STEC.	A/2016.	
Section IX, Page 16, Paragraph 2	Batch determination: each authorized establishment defines the production batches which the inspector in charge should be informed of in the first place whenever said batches undergo any change. By means of Circular Letter 4246/2016, defining a batch from sanitation to sanitation interval is prohibited.	This National Service wishes to clarify that the definition of "batch" is included in 4210 A/2016.	Amend Circular Letter number.

ANNEX II – RESPONSES TO NON-COMPLIANCES FOUND IN THREE OUT OF SIX AUDITED COMPONENTS

1. ***REGULATORY POWER OF THE GOVERNMENT AND REGULATIONS ABOUT FOOD SAFETY AND CONSUMER'S DEFENSE. The impact of the device*** *causes an extrusion of the brain mass through a hole in the skull, and spillage could create unhealthy conditions which will lead to the product contamination. The same finding was observed in the audit conducted by FSIS in 2012.*

Response:

Regarding the finding, this National Service wishes to inform that Circular Letter 4246/2016 was issued. By means of such Circular Letter, the Establishments that are authorized to export to this destination are instructed to develop a SSOP to prevent cross-contamination of meat with SRM.

2. ***GOVERNMENT SANITATION.*** *Regarding the five establishments that were audited, FSIS auditors observed findings related to SPS, which are pointed out in the verification lists of establishments that are included in Annex A to the report. SENASA removed from the list one of the audited establishments that posed a potential contamination risk to products.*

Response:

It is worth noting that prompt Corrective Actions, as well as Corrective Actions with various compliance terms, have been taken during the audit, all of which is reflected on the respective work schedules submitted by the establishments. Such documents are part of the responses to the verification lists submitted by FSIS.

In relation to this finding, SENASA has Circular Letter 4234/2016 in place, in which the procedure to be followed when dealing with a response to a foreign audit is described. In such audit, any Corrective Action taken is verified both by the Official Service and the Regional Competent Authority.

The corresponding documents were sent to SENASA in compliance with the aforementioned Circular Letter in order for the corrective actions to be assessed by the specific technical areas, and for the fact that non-compliances have been remedied to be confirmed.

3. ***SYSTEM OF HAZARD ANALYSIS AND CRITICAL CONTROL POINTS OF THE GOVERNMENT.*** *In an establishment, there was no support for the critical limit of the HACCP Plan. The verification of the HACCP plan revealed that the critical limit for the control of Clostridium perfringens did not include a procedure to monitor the product temperature, but it only included the time span. The "Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) (Annex B)" were used as a support for the critical limit. In Annex B, the need of a ratio between time span and temperature to control the growth of Clostridium spores is described.*

Response:

With regard to this finding, it is worth noting that each farm establishes its own control procedure of *Clostridium perfringens* within the framework of its HACCP, and it should comply with the time and temperature parameters governed by U.S.A. regulations or, according to a specific risk assessment, with other scientifically validated values.

Regarding the observed establishment, in 2004, specific studies about heat penetration and cooling monitoring were performed at the National Institute for Industrial Technology (INTI, for its acronym in Spanish). By means of such studies, it was verified that, under the most unfavorable conditions, on average 4 hours go by from the time products come out of furnaces until they reach 4.4 °C in the geometric center of tubes.

In addition, a study of the cooling curve showed that, until the product reaches 4.4 °C, temperature decrease is steady, stable, and significant; therefore, it may be concluded that temperature monitoring could be disregarded.

In accordance with Annex B, *Compliance Guidelines for Cooling Heat-treated Meat and Poultry Products (Stabilization)*, it is laid down that, in order to reduce the risk of growth of *Clostridium perfringens* in the product, the product should reach a temperature of 4.4 °C in a time span of **no longer than 6 hours and 30 minutes**, and SENASA authorized the establishment to control the time span that went by from the end of cooking until the entry in the plates of the last product tube, with a maximum limit of 1 hour and 30 minutes (critical limit).

It is worth noting that, in order to reinforce the process control, it was agreed that the establishment performs product verification on a weekly basis through temperature measurement in the geometric center of the tube, between 4 and 6 hours since the end of cooking, and results should be recorded on a specific form to the end. The establishment reviewed its HACCP plan for this new verification to be reflected on it.

Dirección de Inocuidad de Productos de Origen Animal.
Paseo Colon 367 6º piso.
Ciudad Autónoma de Buenos Aires.
Tel/Fax: 4121-5290/5291
dipoa@senasa.gov.ar

ANNEX II

GUIDELINES TO OBSERVE AT THE TIME OF COMPLETING THE "FORM OF OFFICIAL VERIFICATION OF FINDINGS/OBSERVATIONS OF FOREIGN AUDITS"

With the purpose of completing the form, please, bear in mind that it presents two sections: the first one includes the heading that includes all relevant data of the audited establishment and the second one contains a table to be completed with the findings/observations as a numbered list, with their corrective actions, preventive measures conducted, dates of remediation and verification, as well as compliance or lack of compliance, which includes the signature of the official veterinarian of the establishment.

The heading is to be completed with the following information at a first instance:

Company name:
Official number:
Domicile:
City/Province:
Country:
Activity:
Products requested:
Head of inspection service: (name)
Regional supervisor: (name)
Date of inspection:

At a second instance, there is a table to be completed line by line with each finding/observation detected by foreign auditors.

Besides, said table has different columns that are explained below:

No.: if any, each finding shall be correlatively numbered.

Finding/Observation: findings detected by auditors during the visit are to be included here, in a detailed fashion (according to the report of the Foreign Audit).

Corrective action: the action adopted by the company is to be stated here, either immediate or mediate, to remedy the non-compliance of the relevant item. In case of remediation by means of a work schedule, or in case additional documents need to be enclosed (E. g.: training schedule, laboratory analysis, photos, etc.) the box corresponding to the corrective action is to be completed with the phrase "SEE ENCLOSED ADDITIONAL DOCUMENTS ANNEX No. …", which is to be provided in an annex and enclosed with the form of reference.

Preventive measure: this section is to be completed with the measures to be adopted preventively by the company to avoid reoccurrence of the non-compliance of the relevant item.

Dirección de Inocuidad de Productos de Origen Animal.
Paseo Colon 367 6º piso.
Ciudad Autónoma de Buenos Aires.
Tel/Fax: 4121-5290/5291
dipoa@senasa.gov.ar

Date of correction: the company is to enter the date when the observation is regularized

Date of verification: the head of the inspection service is to enter the date of verification of the observation.

Compliant: the head of the inspection service is to indicate either “YES” or “NO” (as appropriate), regarding the compliance with the corrective action or preventive measure related to the finding/observation detected by the foreign audit.

Official verification (signature and stamp): the head of the inspection service is to sign and endorse each item once the non-compliance is remedied and verified.

It is worth clarifying that in those cases where the finding/observation is related to the Veterinary Inspection Service, another form is to be drawn up separate from that of the company, which is only to be signed by official staff.

Furthermore, all reports are to be duly signed by the company representative as well as the regional supervisor of SENASA.

Lastly, the form, as well as all supporting documents, is to be submitted to this address both in soft format and printed, with the corresponding signatures, for the purposes of the final report.

Servicio Nacional de Sanidad y Calidad Agroalimentaria
Dirección de Inocuidad de Productos de Origen Animal
Paseo Colón 367, 6º piso, frente
Ciudad Autónoma de Buenos Aires
Tel./Fax: 4121-5290/5291
dipoa@senasa.gov.ar

BUENOS AIRES,

CIRCULAR LETTER No.

TO:
REGIONAL DIRECTORS
THEMATIC COORDINATORS OF AGRI-FOOD SAFETY AND QUALITY
SUPERVISORS
HEADS OF SERVICE

C/C
PRESIDENCY UNIT
GENERAL COORDINATION OFFICE FOR REGULATION AND TECHNICAL ORGANIZATION - DNICA

SUBJECT: Form of official verification of findings/observations of foreign audits

PURPOSE: To establish and harmonize a procedure to order the drawing up of responses to final reports on findings/observations detected during the visit of foreign audits.

SCOPE: all establishments authorized by this National Service for Agri-Food Health and Quality which manufacture products, by-products and derivatives of animal origin.

This is for your information, notification and implementation, and subsequent notification to the company. It is hereby informed that in relation to the recent deviations detected in drawing up technical reports submitted as response to national inspection visits and/or foreign audits, and with the purpose of preventing their reoccurrence, this Directorate lays down a procedure that the Veterinary Inspection Services (VIS) shall take into account to optimize controls and drawing up of relevant clarifications and/or technical statements at the time of submit them as assurance of remediation of observations detected.

Therefore, with the purpose of harmonizing and optimizing the procedure to submit technical reports by the VIS and the Supervisor, the following shall be taken into consideration:

- **Annex I:** *FORM OF OFFICIAL VERIFICATION OF FINDINGS/OBSERVATIONS OF FOREIGN AUDITS"*
- **Annex II:** *Guidelines to complete the form*

The FORM OF OFFICIAL VERIFICATION OF FINDINGS/OBSERVATIONS OF FOREIGN AUDITS and the GUIDELINES TO OBSERVE AT THE TIME OF COMPLETING THE FORM, shall enter into force as of the date of this Circular Letter.

Please, acknowledge receipt of this Circular Letter.

Dr. LEONARDO JORGE MALVESTITI
Dirección de Inocuidad de
Productos de Origen Animal
SENASA

En la fecha _____como responsable autorizado de de la Coordinación Temática del establecimiento N° Oficial firma _____ con mi firma al pie, dejo constancia de haber recibido una copia de la Circular _____ para conocimiento y posterior difusión.

Firma y Aclaración_____

senasa
SERVICIO NACIONAL DE SANIDAD
Y CALIDAD AGROALIMENTARIA

Annex I

”FORM OF OFFICIAL VERIFICATION OF FINDINGS/OBSERVATIONS OF FOREIGN AUDITS”

Company name:
Official Number:
Domicile:
City/Province:
Country:

Activity:
Products requested:
Head of inspection service:
Regional Supervisor:
Date of inspection:

No.	FINDING/OBSERVATION	CORRECTIVE ACTION	PREVENTIVE MEASURES	DATE OF REMEDIATON	DATE OF VERIFICATION	COMPLIANT	OFFICIAL VERIFICATION (signature and stamp)

SIGNATURE AND STAMP OF THE COMPANY _____

SIGNATURE AND STAMP OF THE REGIONAL SUPERVISOR _____

BUENOS AIRES, December 13, 2016

CIRCULAR LETTER No.: 4246

TO: MESSRS REGIONAL DIRECTORS

MESSRS THEMATIC COORDINATORS FOR AGRI-FOOD SAFETY AND QUALITY

MESSRS SUPERVISORS

MESSRS CHIEFS OF SERVICE

CC: OFFICE OF THE PRESIDENT

GENERAL COORDINATION OFFICE FOR TECHNICAL REGULATION AND ORGANIZATION – DNICA (by its initials in Spanish)

SUBJECT: Bovine Spongiform Encephalopathy (BSE); preventive measures to avoid possible contamination of carcasses in establishments authorized to export to the U. S. A.

GOAL: That the establishments authorized to export to the U. S. A. shall have written procedures and records regarding the coming out of brain tissue considered as Specified Risk Material (SRM) for Bovine Spongiform Encephalopathy, after stunning.

SCOPE: All the slaughtering establishments that are authorized to export to the U. S. A. within the framework of the Regulation for the Inspection of Products, By-Products and Derivatives of Animal Origin (Decree No. 4238/68) and that are included in the list of the Food Safety and Inspection Service (FSIS).

You are hereby informed and notified and the company shall be subsequently informed on the steps to be followed in order to comply with the goal of this Circular Letter. Said steps are the following:

1. During stunning by means of the perforation method without air insufflation, which is used as a measure to prevent both nerve tissue from coming out and possible carcass contamination, the mechanically opened skull hole shall be blocked. In case said tissue comes out, it shall be removed prior to blocking the hole.
2. Removal of Risk Material:
    a. Removal shall be tidy and clean, and splashes shall be prevented.
    b. Tools shall be identified for their exclusive use (e. x.: knives with handles of different colors; this should be included and stated in the general tool handling guides within the establishment).
    c. Tools shall be washed and sterilized between one animal and the other (this shall be also included in the corresponding guides of the establishment).
    d. The material removed shall be disposed of in plastic bags bearing a violet cross and the acronym MRDEEB, and intended for such purpose. Such material shall be denatured with methyl violet for it to be subsequently seized.
3. The HACCP Plan shall be reviewed and this step (foramen blocking) shall be considered as a CP.

4. The VIS shall check and register its compliance with Circular Letter No. 3531/2003, Annex No. 2, “Humane Treatment”, when palpebral reflexes are verified.
5. Circular Letter No. 3528/2003 shall be complied with.

The establishment shall be responsible for the strict compliance with the provisions hereof that shall be immediately implemented.

The staff that performs this duty shall be qualified for such purpose.

The fact that establishments do not comply with the items described above shall be sufficient grounds for suspending their certification for the U. S. A.

Please acknowledge receipt of this Circular Letter.

Sincerely yours,

Ricardo Blas MAGGI

Director for Safety of Animal Products

SENASA

On_____, in my capacity as Thematic Coordinator of the official establishment No.:_____ of the firm: _____, and by signing below, I acknowledge that I have received a copy of Circular Letter No._____ for it to be known and subsequently spread.

_____

Signature and typed or printed name