USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Fernando Carreras Vaquer
Subdirector General
Subdireccion General de Sanidad Exterior
Ministerio de Sanidad, Politica Social e Igualdad
Paseo del Prado 18-20
28014 Madrid

Dear Dr. Carreras Vaquer,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Spain's meat inspection system from September 16 through October 6, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of Spain are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at international.audit@fsis.usda.gov.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

SPAIN

SEPTEMBER 16 TO OCTOBER 6, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

March 7, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 16 to October 6, 2015. The purpose of the audit was to determine whether Spain's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Spain currently exports the following categories of pork products: Raw – intact; raw – not intact; fully cooked – not shelf stable; not heat treated – shelf stable; and heat treated – not fully cooked – not shelf stable.

The audit focused on six system equivalence components: Government Oversight (Organization & Administration), Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

The audit findings indicated a need for improvement in Government Oversight related to conducting periodic assessments of the technical compatibilities of official personnel at the in-plant inspection levels of the organization. FSIS also identified some operational (or procedural) weaknesses related to the Sanitation and HACCP Systems, none of which were significant.

An exit meeting was held on October 6, 2015, in Madrid, Spain with representatives from the Ministry of Health, Social Services and Equality (MSSSI, Spanish name: *Ministerio de Salud, Servicios Sociales, e Igualdad*). The preliminary audit findings were presented by FSIS. During the audit exit meeting, the Central Competent Authority (CCA) noted that it has already begun to address some of the audit findings by implementing immediate corrective actions as described herein. FSIS will evaluate for effectiveness information provided by Spain.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Spain's food safety system from September 16 to October 6, 2015. The audit began with an entrance meeting held on September 16, 2015, in Madrid, Spain with the participation of representatives from the Central Competent Authority (CCA) – Ministry of Health, Social Services and Equality (MSSSI, Spanish name: *Ministerio de Salud, Servicios Sociales, e Igualdad*), and an FSIS auditor. Also in attendance at this meeting were representatives from the Ministry of Agriculture, Food and Environment (MAGRAMA, Spanish name: *Ministerio de Agricultura, Alimentación, y Medio Ambiente*), the Ministry of Economy (MINECO, Spanish name: *Ministerio de Economía*), and from the Autonomous Communities (ACs) of Catalonia, Castilla-León, and La Rioja.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Testing Programs, and (6) Government Microbiological Testing Programs. FSIS also assessed country's performance as related to product types and volumes, frequency of prior audit-related site visits, Point-of-Entry (POE) testing results, government oversight activities, and the testing capacities of government laboratories. The review process included an analysis of data collected by FSIS over a two-year timeframe, in addition to information obtained directly from the CCA, through a Self-Reporting Tool (SRT).

The FSIS auditor was accompanied throughout the audit by representatives from the CCA office, the Catalonia and Castilla y León Autonomous Communities (ACs), and from local inspection offices. Administrative functions were reviewed at CCA headquarters, two (2) Autonomous Communities (ACs) offices, and six (6) local inspection offices, during which the auditor evaluated the implementation of management control systems in place that ensure that the national system of meat products inspection, verification, and enforcement is being implemented as designed.

A sample of 6 establishments was selected from a total of 19 establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2, the FSIS regulations addressing equivalency determinations for foreign country inspection systems.

Additionally, one government laboratory that conducts microbiological and residue analyses was audited to verify the CCA's ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority Offices	Central	1	Ministerio de Salud, Servicios Sociales, e Igualdad (MSSSI), Madrid
	Autonomous Community	2	Catalonia and Castilla y León
	Local	6	Riudellots de la Selva, Albelda de Iregua, Rasillo de Cameros, Sotoserrano, Tamames, Fuentes de Béjar
Laboratories		1	Centro Nacional de Alimentación, Majadahonda (Residue and Microbiology) - Government Laboratory
Establishments		6	• Two (2) porcine slaughter and processing establishments • Four (4) porcine processing establishments

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

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

In addition, the auditor verified that the system implemented and enforced United States equivalent European Commission (EC) regulations and directives:

- Regulations (EC) Nos. 852/2004; 853/2004; 854/2004; 882/2004; 2073/2005; 178/2002,
- Spain's Law 17/2011 on food safety and nutrition,
- Spain's Law 33/2011 on public health controls,
- Spain's Royal Decrees 195/1998, 118/1998, 1976/2004, and 191/2011, and
- Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23.

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

Currently, FSIS has the following equivalence determinations in place for Spain:

- Generic *Escherichia coli* (*E. coli*):
  As applicable to all European Union (EU) exporting countries, testing for *Enterobacteriaceae* and Total Viable Count (TVC) in raw product may be substituted for generic *E. coli* testing,
- Testing for Salmonellae using PNTCNA_BA002,
- PNTCNA _IB001 method for species testing, and

- PNTCNA_BA001 *Listeria monocytogenes* method.

III. BACKGROUND

Spain is eligible to export pork products. Between October 1, 2013, and April 30, 2015, FSIS import inspectors performed 100% re-inspection for label verification and certification on 9,640,353 pounds of meat products exported by Spain to the United States. FSIS also performed re-inspection on 1,918,553 pounds at POE for additional types of inspection (TOI). A total of 5,494 pounds were refused entry for issues not involving food safety concerns (e.g., missing shipping marks, container shipping damage). Spain currently exports the following pork products: Raw – intact; raw – not intact; fully cooked – not shelf stable; not heat treated – shelf stable; and heat treated – not fully cooked – not shelf stable.

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

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

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

The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and on-site observations made by the FSIS auditor at government offices, establishments, and the reference microbiology laboratory. The responsibility for Spain's meat inspection control systems lies with two Ministries, MSSSI and the Ministry of Agriculture, Food and Environment (MAGRAMA, Spanish name: Ministerio de Agricultura, Alimentación, y Medio Ambiente). The chain of command begins with the MSSSI, the Central Competent Authority (hereinafter called the Ministry of Health or CCA), which has principal responsibility for food safety. In particular, it had responsibility for the direct authorization and supervision of the export establishments, developing and implementing controls over the products they produce, and ensuring that, from a public health perspective, establishment operating procedures and production processes are safe.

The CCA responsibilities cover food products of animal and vegetable origin, all kinds of foods, drugs, chemical products, sanitary/phytosanitary products for human use, and public health controls. The Ministry of Agriculture, Food and Environment is responsible for animal health and welfare, animal feedstuffs, veterinary drugs, and traceability from the farms to the slaughterhouses. There are some issues for which both ministries are competent, e.g., foods of animal origin, drugs.

There is also a Spanish Agency of Consumers Affairs, Food Safety and Nutrition (AECOSAN, Spanish name: *Agencia Española de Consumo, Seguridad Alimentaria y Nutrición*) which is under the authority of the Health Minister but is an independent, self-managed body. Its responsibilities include the coordination of the competent authorities for national health control, the enactment of food regulations, the preparation of scientific reports for food safety issues, and representation of the competent bodies before the EC regarding the development of European requirements. However, it has no food inspection responsibilities.

Spain is administratively divided into 17 ACs and the 2 autonomous cities of Ceuta and Melilla. The ACs are responsible for official controls except with respect to import and export controls. Under the Spanish Constitution (Article 148.1), the Statutes of Autonomy and corresponding Royal Decrees transferring functions and services, the ACs have exclusive responsibility for the implementation of control systems in Spain for food products that are to be made and sold within the country. Following the decentralization of government functions in the 1980s, the central government transferred to the ACs the responsibilities for public health regulation and enforcement, including food control. The central government, however, maintains exclusive responsibilities for international aspects of public health, including the preparation of meat products for export.

During the audit, FSIS noted that the CCA maintains exclusive responsibility for implementing the general principles of health, providing direct oversight for ACs and transposing the EC regulations into Spanish law to guarantee the consistency of the national inspection system. In addition, the CCA has the absolute authority and responsibility to require uniform implementation of FSIS requirements in those ACs that contain United States certified establishments. At this time, the following eight ACs contain United States certified establishments: Andalucía, Aragón, Castilla - La Mancha, Castilla - León, Catalonia, Extremadura, La Rioja, and Valencia.

The inspection program is funded by the national and the regional governments. The General State Budget grants the ACs their own authority to establish their own regional budgets. Each AC designs and controls its own budget according to allocations provided to them from the central government. Personnel in charge of supervision, verification, and inspection activities within the system are employees of the Government of Spain. Personnel working at the official laboratories are also government employees who are subject to the same administrative policies that apply to officials in the inspection task force.

Within the CCA, the department with inspection and control responsibilities regarding exports and imports is the General Directorate of Public Health, Quality, and Innovation (DGSPCI, Spanish name: *Dirección General de Salud Pública, Calidad, e Innovación*) and its General Sub-directorate General for Foreign Health (SGSE, Spanish name: *Subdirección General de Sanidad Exterior*). Registration, certification, and control of Import/Export food establishments is conducted by SGSE, which verifies that meat establishments fulfill official requirements prior to being granted certification to export, whereas domestic production and trade is controlled by the ACs on the basis of their own responsibilities. Additionally, SGSE has direct authority over the

official Chemical Residue and Microbiological laboratories of the system that perform analysis of meat products exported to the United States.

Spanish establishments interested in obtaining approval to export products regulated by FSIS to the United States submit an application to the External Livestock Commerce (CEXGAN, Spanish name: *Comercio Exterior Ganadero*) unit of MAGRAMA. Once MAGRAMA completes its review of the application, the SGSE will request a preliminary report of the establishment from the AC Official Veterinary Service (SVO, Spanish name: *Servicios Veterinarios Oficiales*) where the establishment is located. After receiving a report from the AC SVO indicating the new establishment is compliant with United States requirements, the CCA conducts an assessment of the facility to verify its compliance with FSIS requirements Information about the application process is available on the MSSSI website. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing United States certified establishment to maintain its eligibility to export to the United States. The FSIS auditor reviewed electronic and hard copy documents maintained by government officials at the CCA headquarters or ACs offices and verified that registration, initial equivalence determinations, and certification are conducted by officials of SGSE.

The auditor noted that the CCA relies on the ACs for the enforcement of the public health regulations regarding exports. There are scheduled coordination meetings, three to four times per year, between the CCA and the ACs. The FSIS auditor reviewed coordination meeting notes at Catalonia and Castilla – León Autonomous Communities. The meeting notes included topics intended to ensure that inspection officials were aware of specific inspection requirements that pertain to Spain's meat products export to the United States. These topics included official control recommendations, program revisions or instruction modifications; uniform application of inspection procedures; annual proposal for frequency of periodic supervision based on risk analysis; export certification activities and FSIS requirements such as RTE sampling (*Salmonella* and *Listeria*) and species verification testing; and regulatory oversight and enforcement procedures (suspension or Notice of Intent to Delist) by both the CCA and ACs. No concern arose as a result of these reviews.

The CCA manages and maintains a computer based application named QUAESTOR to manage inspection processes in United States certified establishments. The CCA can grant access within QUAESTOR to in-plant inspection officials, AC personnel, and establishment individuals. This computer program has created a uniform information database that includes inspection forms and procedures that are used by SVOs assigned to United States eligible establishments throughout the country. The program has separate tabs for Sanitation Standard Operating Procedure (SSOP), HACCP, product and process control, pre-shipment reviews, equipment, and hygiene controls regarding operations and personnel. In-plant personnel use the application to document results of the daily inspection verification tasks they perform. When non-compliance is observed, it is documented within QUAESTOR. The system also generates standardized forms that are used by the SVO to notify the establishment of non-compliance with requirements. Establishments can document their responses to non-compliances either on the standardized form or by providing a response within QUAESTOR.

Inspection personnel demonstrated the availability and use of QUAESTOR by accessing information requested by the FSIS auditor. This information included an overview of the last 180 days of in-plant

verification of HACCP, sanitation, and enforcement activities. In addition, AC supervisors and the CCA demonstrated how they would review and analyze the inspection data to identify trends and effectiveness of corrective actions. As a result of these presentations, the FSIS auditor concluded that in-plant inspection personnel had proper training to utilize the program, and that AC supervisors have provided adequate oversight to ensure the proper implementation of the program.

Within QUAESTOR, official personnel are granted access by the CCA only to establishments to which they provide inspection coverage. Establishment personnel are only granted access to specific parts of the application, such as the section to which they can provide answers to non-compliances. This computer program has created a uniform database of information which included inspection forms and procedures to be used by the official veterinarians assigned to the United States certified establishments throughout the country.

The auditor reviewed periodic supervisory reviews at the CCA headquarters, two ACs, and six local inspection offices. The CCA and ACs supervisors were using a standard checklist form for conducting their periodic supervisory reviews. This form addresses contamination control, disease control (including ante and post mortem requirements), control of residues (including residue program and sampling), control of prepared products (including re-inspection, restricted ingredients, transport of product), economic control (including export certificate, equivalency status), and compliance with HACCP, SSOP, and Sanitation Performance Standard (SPS) requirements. FSIS also verified that upon conclusion of the supervisory review, both the CCA and AC supervisory officials prepared and delivered a copy of their review to the establishment management that detailed the results of the review and any expected corrective actions.

The AC is the party responsible for designating and overseeing the activities of the Official Veterinarians (OV) in establishments authorized to export to the United States. The ACs recruit OVs from state veterinary universities and provide them with required general training. The public officials of the ACs (including in-plant inspection personnel) have the same status as public officials of the national government to take official control actions in United States certified establishments.

Each year the CCA and ACs schedule training activities for the OVs. The FSIS auditor reviewed training records for 2013 and 2014 at the CCA and at the two audited ACs. This review showed that in-plant inspection personnel have successfully completed training that included control alternatives for *Listeria monocytogenes*, lethality treatments, sampling and methods of analysis, regulatory control actions to take in response to positive results in RTE sampling, control of fecal/ingesta/milk contamination, HACCP/SSOP/SPS inspection verification methodology, and the official verification program for RTE production lines. The CCA makes the training materials available for review on its website.

At both swine slaughter establishments audited, the auditor reviewed *Salmonella* sampling methodology on swine carcasses and verified that official samples are shipped to accredited government laboratories. This process was under the oversight of the CCA and ACs and in accordance with FSIS equivalency requirements.

The FSIS auditor verified that the CCA provides laboratory oversight by conducting a verification audit at the central microbiology laboratory. Spain's laboratories are part of the technical support of the CCA inspection system and maintain accreditation through the Spanish Accreditation Body (ENAC, Spanish name: *Entidad Nacional de Acreditación*). This aspect of the inspection system is further described in the Microbiological and Chemical Residue Program components portion of this report, below. The auditor also verified that the laboratory personnel at the audited microbiology laboratory received training on analytical methodology, laboratory procedures, and quality control practices to meet the needs of the microbiological testing control programs.

FSIS' audit identified that there was a lack of documentation to determine the method used to assess and develop the adequacy of the inspection skills of individual in-plant inspectors on an ongoing basis to ensure they are performing their duties in accordance with prescribed inspection methods and procedures. Although the CCA and the AC provide supervision of personnel conducting official inspection activities, the methods in use to assess the technical competence and performance of individual in-plant inspection officials do not demonstrate that individual inspector performance is being evaluated periodically.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety 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.

The auditor's evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. The FSIS auditor verified that official inspection and verification activities followed responses from the SRT and the supporting documentation. There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the CCA.

This evaluation helped to verify that Spain's inspection system has statutory authority to deliver inspection to all certified establishments, described in Regulations (EC) Nos. 852, 853, and 854, to provide requirements for humane handling and slaughter of livestock, ante and post-mortem inspection, control over establishment construction/facility/equipment, control over inedible and condemned materials, as well as daily inspection and periodic supervisory reviews of the certified establishments.

The CCA has regulatory requirements in place that require that official inspection personnel, laboratories, and establishments meet the requirements of importing countries. The publication

entitled *Procedimientos Inspección Establecimientos Autorizados EEUU, Rev. 6, 31 de Enero 2014* (Translation: Inspection Procedures in Establishments Authorized for the United States, Revision 6, January 31, 2014) provides details about the responsibilities the DGSPCI and the AC with regards to assignment, training, and supervision of official personnel assigned to United States eligible facilities. The *Procedimientos Inspección Establecimientos Autorizados EEUU* also provides general guidance to in-plant inspection personnel on the official HACCP/SSOP/SPS and Pathogen Reduction (PR) inspection tasks that they are to routinely perform at United States eligible establishments.

During the on-site audit of both swine slaughter establishments, the FSIS auditor observed inspection personnel while they performed ante-mortem inspection activities at the holding pens. Official veterinarians conduct ante-mortem inspection on the day of slaughter by reviewing the in-coming registration and identification documents with each load/truck and observing all swine at rest and in motion in designated holding pens in order to determine whether the animals are fit for slaughter. There were separate pens marked for examination of suspect animals. The FSIS auditor observed and verified that all animals had access to water at all times in all holding pens, including the suspect pen, and that, if the animals were held overnight, feed was provided. The auditor concluded that the implementation of ante-mortem inspection was in compliance with Regulations (EC) No. 854/2004, which FSIS has previously determined is equivalent to comparable FSIS regulatory requirements.

The FSIS auditor also assessed post-mortem inspection at both United States certified swine slaughter establishments audited. The auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. Inspection personnel in United States eligible establishments were official personnel employed by the ACs who were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of inspection personnel examining the swine heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes were made in accordance with procedures recognized as equivalent to FSIS requirements. The design of the post-mortem inspection stations, including proper lighting and the number of on-line inspectors, met United States expectations and also met Spain's requirements.

The ACs supervisory officials conduct periodic supervisory reviews of certified establishments in accordance with CCA written instructions. The CCA determines the frequency of supervisory reviews based on risk assessment modules for individual establishments on an annual basis. The periodic supervisory reviews have two portions. The first portion determines whether an establishment's food safety system continues to meet regulatory requirements for exporting to the United States. The second portion evaluates the performance of inspection personnel at certified establishments.

The FSIS auditor reviewed the inspection verification and enforcement records that were generated by in-plant inspection personnel on a daily basis within QUAESTOR as well as periodic supervisory review reports prepared by the CCA and the ACs. Spain has adopted FSIS Directive 5000.1 and its procedures concerning issuing non-compliance reports (NR). The FSIS auditor verified that the inspection personnel have identified and documented deficiencies in an

NR. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventative measures. At the six audited establishments, the FSIS auditor reviewed a sample of open and closed NRs issued for sanitation standard operating procedures (SSOP), HACCP, and SPS non-compliances.

The FSIS auditor also reviewed several supervisory reviews to assess the enforcement capability of the inspection personnel and the adequacy of establishment's corrective actions. No concerns arose as the result of these observations. The conditions observed in the audited establishments matched the supervisory reviews, and there was no indication that there were any non-compliance trends with respect to SSOP, HACCP, or SPS at the audited establishments.

In conclusion, Spain's meat inspection system has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the United States.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS's program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOP.

The evaluation of this component included a review and analysis of Spain's documentation, including Regulations (EC) Nos. 852/2004, 853/2004, and 854/2004, previously submitted by the CCA as support for the responses provided in the SRT and observations made by the FSIS auditor during the on-site audit of government offices and three of the certified establishments.

The FSIS auditor reviewed legislation, regulations, and official instructions, including Regulations (EC) No. 852/2004 - Article 4 and Annex II, Chapter V, Regulations (EC) No. 853/2004- Annex III, Section I, Section VI, Regulations (EC) No. 854/2004- Article 4, Regulations (EC) No. 178/2002, Articles 6, 7, 53, 54, 55, 56, 57, 58, and 60, Regulations (EC) No. 882/2004, Title II, Chapter II, Article 10; Chapter II Article 4.3, (b), Council of 29 April 2004 on the hygiene of foodstuffs, and verified that the CCA exercises its legal authority to require industry operators to develop, implement, and maintain sanitations programs sufficient to prevent direct product contamination and the creation of insanitary conditions.

The CCA demonstrated that it enforces aforementioned EU sanitary regulations which FSIS has determined to be equivalent to FSIS requirements. In addition, Spain has adopted FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416. The in-plant inspection personnel at certified establishments conducted verification of sanitary conditions in accordance with FSIS Directive 5000.1 methodology and the aforementioned requirements, which included the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures.

The auditor observed that certified establishments are required to conduct product contact surface testing in both raw and ready-to-eat (RTE) production areas to demonstrate the adequacy

of the sanitation procedures. The in-plant inspectors entered sanitation verification data into the QUAESTOR program which can be analyzed by the AC and CCA to detect trends of non-compliance.

The FSIS auditor reviewed the design and implementation of sanitation programs at the audited establishments. The FSIS auditor observed in-plant inspectors conducting pre-operational sanitation verification of slaughter and processing areas in two of the audited establishments. The in-plant inspection's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for in-plant inspector pre-operational sanitation verification activities. In addition, the FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at all audited establishments. These verification activities included direct observation of operational process and review of the establishment's operational records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection verification records for the same time period.

The FSIS auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees specified as being responsible for the implementation and monitoring of the SSOP procedures authenticated these records with initials or signatures and the date observations were made. No concern arose as the result of this review.

Although the auditor verified that sanitation verifications activities by the CCA were performed in accordance with CCA requirements, while conducting a walk-thru of the facilities, the auditor made the following observations related to SPS in establishments eligible to export to the United States:

- In one slaughter establishment, beaded condensation was observed on two refrigeration units located in the hallway that leads into the boxed product freezers. No direct product contamination was observed.
- In one processing establishment, a door leading from the outside to an area that could hold exposed products was not properly sealed so as to prevent the entrance of vermin. No evidence of pests was observed.
- In one processing establishment, a flying insect was observed in a processing room. The establishment took immediate action to eliminate and remove the insect from the room and sanitize the area. No direct product contamination was observed.
- In one processing establishment, packaging materials were stored in close proximity to a wall, interfering with the ability of the inspector to examine the area.

In all cases, in response to the observations noted above, the in-plant inspection team, the AC, and the CCA officially notified the establishments by issuing administrative actions to implement immediate corrective actions, including measures to restore the sanitary conditions. Prior to completing the audit, the FSIS auditor was able to verify that corrective actions and preventive measures addressing the aforementioned SPS deficiencies were implemented.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS confirmed that the CCA inspection system provides requirements for sanitary handling of products and for the development and implementation of SSOPs, although the auditor did observe non-compliances with these requirements. The CCA and the ACs took measures to ensure that certified establishments implement effective SSOPs and other sanitary measures that prevent direct contamination and adulteration of products destined for the United States.

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

The fourth of six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan. In Spain, this requirement is embodied in Regulations (EC) No. 852/2004.

The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and on-site observations made by the FSIS auditor during the audit of government offices and all establishments audited.

The FSIS 2012 final audit report made note of several systemic findings within the HACCP systems equivalence component. In response to these findings, the CCA proffered corrective actions in the design and execution of the food safety inspection system concerning *Listeria monocytogenes* (*Lm*) control programs. During the current audit, the FSIS auditor was able to verify that all the proffered corrective actions had been adequately implemented by the CCA.

The FSIS auditor reviewed the CCA's document "*Cuestionario de Autorización Carnes Frescas y/ó Productos Cárnicos Estados Unidos de América*" (translation: Questionaire for the Authorization for Fresh Meat and/or Meat products for the United States of America) which outlines required legislation for HACCP implementation. This document refers to HACCP related requirements cited in Order April 4, 1995, Notice No, 1/95, Notice No. 5/97, and part 417 of title 9 of the Code of Federal Regulations. Document reviews conducted by the FSIS auditor at the CCA, ACs, and establishment offices revealed that the CCA exercises its legal authority to require industry operators to develop, implement, and maintain HACCP programs.

The CCA has adopted and enforces FSIS's HACCP regulatory requirements prescribed in 9 CFR Part 417. The in-plant inspection personnel at certified establishments conducted daily verification of HACCP plans in accordance with FSIS Directive 5000.1 methodology and HACCP requirements. This verification includes an evaluation of written HACCP plans and their contents, conducting reviews of HACCP records, performing observation of monitoring and verification activities, and verifying implementation of corrective actions when there is a deviation from the critical limits. The in-plant inspectors enter HACCP related observations into the QUAESTOR program.

Documents reviewed by the FSIS auditor included regulatory standards, training materials, and regulatory guidelines issued by the CCA. The FSIS auditor also assessed the adequacy of the HACCP program verification activities conducted by government officials and establishment operators at the establishment level by observing verification activities and reviewing electronic

and hard copy versions of monitoring and verification records generated by operators and in-plant inspection officials. The observations, reviews, and analysis of information conducted by FSIS revealed that Spain's meat inspection system imposes on operators of United States certified establishments regulatory requirements for the development, implementation, and maintenance of HACCP programs as set forth in the EU and FSIS regulations. The official inspection verification activities include an assessment of the design and execution of the establishment's HACCP programs, including monitoring, corrective actions, record keeping, and verification activities. Furthermore, supervisory reviews by the ACs and CCA of HACCP verification activities by inspection personnel were conducted and were well documented.

The FSIS auditor reviewed records for the zero tolerance CCP generated within the last six months at both slaughter establishments audited. In addition, FSIS auditor reviewed the in plant inspection's zero tolerance CCP verification records for visible ingesta, feces, and milk on swine carcasses. No trends were detected as the result of these document reviews.

The FSIS auditor observed the inspection personnel conducting HACCP hands-on verification activities at the zero tolerance CCP and also made a direct examination of swine carcasses. The auditor and inspection personnel did not observe any deviations from the critical limits. The CCP location met Spain's requirement including the adequate illumination for proper examination of carcasses.

The FSIS auditor reviewed both official as well as establishment records at all audited establishments manufacturing RTE products which confirmed that, to ensure that *Lm* is prevented from contacting any post-lethality exposed RTE product regardless of whether the product supports growth or not (i.e., a zero tolerance for *Lm*), there is on-going testing for *Lm* in the finished product, on food contact surfaces (FCS), and in the processing environment as mandated by the CCA. The FSIS auditor verified that finished RTE product was being sampled by official inspection personnel for *Lm* and *Salmonella spp.* and tested by validated analytical methods at the government laboratories. In addition to conducting *Lm* testing, establishments manufacturing not heat treated – shelf stable products, which are further processed by curing, drying, or a fermenting processing step as the sole means by which the product achieves food safety, included monitoring of product Aw and pH in their processes. The HACCP plan design included supporting documentation for not heat treated – shelf stable products that consisted of several types of documents, such as peer reviewed scientific articles and challenge and inoculated pack studies. Data gathered by the establishment in-plant, consisting of microbiological test results, measurements of A_w and pH of products, and in-plant observations, was available and presented to the auditor at all audited establishments that manufacture not heat treated – shelf stable products to demonstrate that the control measures as implemented help establishments achieve intended food safety objectives towards eliminating *Lm* and *Salmonella spp*. in finished products.

The FSIS auditor verified that the in-plant inspection personnel stationed in slaughter and processing establishments conducted and documented official daily verification activities related to HACCP in accordance with regulatory requirements. Additionally, the inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping in

accordance with Regulations (EC) No. 852/2004 and Regulations (EC) No. 882/2004. Furthermore, the supervisory veterinary inspector and lead auditor conducted reviews of inspection personnel's HACCP verification activities, and these reviews were well documented.

The FSIS auditor verified that in-plant inspection personnel executed HACCP verification activities in accordance with Spain's regulatory requirements. The auditor made the following observation while evaluating the HACCP component:

- In one establishment, the hazard analysis and flow chart were missing one of the steps observed to be taking place in the packing/labeling room (9 CFR 417.2).

The above observation was corrected by the establishment by adding the missing step to the flow chart and the hazard analysis. During the exit meeting, the CCA provided supporting documentation that the corrective action was implemented by the establishment and verified by inspection personnel.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Chemical Residues. The inspection system is to present a chemical residue control program, organized and administered by the national government, that 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.

During the on-site audit, the FSIS auditor reviewed Spain's chemical residue control programs at the CCA's headquarter, two AC offices, and two slaughter establishments certified as eligible to export products to the United States to verify the implementation and enforcement of regulatory requirements. The FSIS auditor interviewed the CCA officials and the in-plant inspectors to verify the proper implementation of the National Residue Program. The auditor verified that Spain's residue control program is designed and conducted in accordance with Council Directive 96/23/EC of 29 April 1996 as well as Regulations (EC) No. 882/2004. The CCA responsibilities include obtaining information when positive or violative results occur, identifying the animal and farm of origin, investigating the cause of the violation at the farm, safeguarding the public health by product disposition, intensifying the checks on the animals and products from the farm, and imposing criminal or administrative penalties against any person who is responsible. Council Directive 96/23/EC of 29 April 1996 has been recognized as equivalent by FSIS. The FSIS review indicated that Spain's national residue testing program for 2015 was being followed and was on schedule.

The FSIS auditor reviewed, in the government laboratory, records related to sample handling, sample arrival temperature, sampling frequency, timely analysis, date reporting, analytical methodologies and matrices, equipment operation and detection levels, intra-laboratories check samples, and quality assurance programs. The auditor's review found that the laboratory conditions, records generated, and results of past audits met EN ISO/IEC 17025:2005 standards. The FSIS auditor did not identify any deficiencies or areas of concern during the audit of the

official laboratory. The staff and management of the visited laboratory are knowledgeable about and apprised of Spain's testing requirements for products destined for the United States. The FSIS auditor received copies of the scopes of accreditation for chemical testing for the NRL by Spain's National Accreditation Entity (ENAC, Spanish name: Entidad Nacional de Acreditación). The FSIS auditor concluded that laboratory personnel are qualified, are adequately trained, are subject to proficiency testing, and are capable of conducting analytical methods and that the residue laboratories demonstrated the ability to produce timely and accurate data.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and on-site observations made by the FSIS auditor at government offices, establishments, and the national reference microbiology laboratory.

During the national reference laboratory visit, verification focused on the qualification of analysts, sample receiving and handling, analytical methodology, data reporting, maintenance of facilities and equipment, and corrective actions. The auditor reviewed the results of the annual audits of this laboratory by the CCA and ENAC. These audits have reported a few non-conformances which were addressed and corrected by the laboratory's quality control. This laboratory is IS0 17025:2005 accredited in accordance with ENAC standards.

In accordance with Regulations (EC) No. 2073/2005 and MSSSI Circular No. 1/2013, Spain requires United States eligible slaughter establishments to assess the effectiveness of sanitation and process control by either sampling and testing for generic *E. coli* in raw carcasses as established in 9 CFR 310.25 or by testing for *Enterobacteriaceae* and Total Viable Count (TVC) in raw meat product, a procedure acceptable for all EU exporting countries and found equivalent by FSIS. The auditor reviewed the establishments' written programs, and the official inspection records did not present any concerns.

The FSIS 2012 final audit report made note of several systemic findings within the equivalence component for Microbiological Testing Programs. In response to these, the CCA proffered corrective actions in the design and execution of the food safety inspection system concerning *Lm* control programs. During the current audit, the FSIS auditor was able to verify that all corrective actions were adequately implemented by the CCA.

RTE control program records were reviewed at CCA headquarters and four establishments producing RTE products. While on-site, the auditor verified that the CCA had adopted FSIS regulatory requirements related to the control of *Lm* in the post-lethality RTE environment of the

processing facilities as outlined in 9 CFR Part 430. The CCA administers a regulatory microbiological verification program that includes additional post-lethality exposed RTE product sampling at meat processing establishments that are eligible for export to the United States. This program differs from the national microbiological verification program administered by the ACs for products that are destined for the EU market. Product destined for the United States is produced and handled in a manner to prevent any contamination of post-lethality exposed RTE product with *Lm* regardless of whether the product supports growth of *Lm* or not. The CCA provided evidence that United States-destined product is not simply tested to ensure the absence of detectable *Lm*, but that controls are in place to prevent contamination with any detectable *Lm*.

FSIS further verified that the CCA has a written enforcement action plan for the official microbiological verification sampling program that outlines the CCA's response when *Salmonella* or *Lm* are detected positive in RTE products. Based on FSIS requirements that are adopted by Spain, RTE product is considered adulterated if it contains *Lm*, or if it comes into direct contact with a food contact surface that is contaminated with *Lm*.

X. CONCLUSIONS AND NEXT STEPS

The audit findings reveal a need for improvement in Government Oversight related to conducting periodic assessments of the technical capabilities of official personnel at the in-plant inspection levels of the organization. FSIS also identified some operational (or procedural) weaknesses related to sanitation, none of which were significant. During the audit exit meeting, the CCA noted that it has already begun to address some of the audit findings by implementing immediate corrective actions as described herein.

An exit meeting was held on October 6, 2015, in Madrid, Spain with representatives from the Ministry of Health, Social Services and Equality (MSSSI, Spanish name: *Ministerio de Salud, Servicios Sociales, e Igualdad*). The preliminary audit findings were presented by FSIS. FSIS will evaluate any information provided by Spain, including the submittal by the CCA of proposed corrective actions in response to the audit findings.

Appendices

Appendix A: Individual Foreign Establishment Audit Checklist
Appendix B: Spain's Response to Draft Final Audit Report (when available)

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
Frigoríficos Costa Brava Ct. De Riudellots a Cassa S/N Riudellots de la Selva Girona	9/22/15	33	Spain
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

41. Beaded condensation was observed on two refrigeration units located on the hallway which leads into the boxed product freezers. The establishment immediately took corrective action and removed the condensation.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

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
Grupo Empresarial Palacios Alimentación, S.A. Ctra. Logroño S/N Albelda de Iregua La Rioja	9/24/15	16	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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	X
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

36. While conducting a traceback exercise to determine that all necessary export documentation was in place in support of an export certificate issued by the authority, the necessary documentation to support this was not located within the file. A follow-up investigation revealed that the missing document had been in fact, placed in the wrong file.

38. Observed one doorway leading from the outside of the building into the hallway by which drying rooms are accessed for loading of product which had a gap between the bottom of the door and its frame of approximately 0.5 inches, which could allow pests to enter into this area. Inspection personnel immediately notified the establishment and the establishment immediately programmed correction of the deficiency by their maintenance personnel. There was no evidence of pests in the immediate area.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

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
Industria Cárnicas El Rasillo, S.A. San Mamés S/N El Rasillo La Rioja	9/25/15	24	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment September 25, 2015 | Est. 24 | Industria Cárnicas El Rasillo, S.A., El Rasillo, La Rioja | (P) | Spain

There were no deficiencies/observations recorded.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

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
Marcos Sotoserrano, S.L.U. Carretera Coria 4 Sotoserrano Salamanca	9/29/15	32	Spain
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment September 29, 2015 | Est. 32 | Marcos Sotoserrano, Sotoserrano, Salamanca | (P) | Spain

22/51. The establishment's Hazard Analysis and flow charts were missing one of the steps observed in the packing/labeling room. The observed non-compliance was corrected by the establishment immediately.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

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
Embutidos Fermín S.L. Polígono Industrial Las Navas, 21 Tamames Salamanca	9/30/15	27	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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	X
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	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment September 30, 2015 | Est. 27 | Embutidos Fermín S.L., Tamames, Salamanca | (P) | Spain

38. While visiting the facility, a flying insect was observed in a processing room. The establishment took immediate action to eliminate and remove the insect and sanitize the area. No product contamination was observed or detected.

46. In room where packaging material was stored in the basement, packaging materials were stored in proximity to the wall, interfering with the ability of the inspector to examine the area.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

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
Matadero Frigorífico de Fuentes El Navazo Polígono Sector UBZ'1 Parcela 2 Fuentes de Béjar Salamanca	10/01/15	34	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment October 1, 2015 | Est. 34 | Matadero Frigorífico de Fuentes El Navazo, Fuentes de Béjar, Salamanca | (S/P) | Spain

There were no observations/findings.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez, DVM	

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

SECRETARÍA GENERAL DE SANIDAD Y CONSUMO

DIRECCIÓN GENERAL DE SALUD PÚBLICA, CALIDAD E INNOVACIÓN

SUBDIRECCIÓN GENERAL DE SANIDAD EXTERIOR

Dra. Jane H. Doherty

International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service

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

Madrid March, 1 2016

In relation to the draft audit report as regards an audit conducted by FSIS on Spain´s meat inspection system from September 16 to October 6, 2015, we agree with the overall content of the report. Specifics comments are explained at the annex of this letter.

Finally, the audit findings reveal a need for improvement in Government Oversight related to conducting periodic assessments of the technical capabilities of official personnel at the in-plant inspection levels of the organization. We are glad to inform that we have re-evaluated the supervision procedure. This procedure is now in draft step. It is foreseen it will be in force by mid-April, after performing training activities related to it.

Sincerely,

Fernando Carreras Vaquer
Deputy Director General

SUBDIRECCIÓN GENERAL
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SPECIFIC COMMENTS

- Page 4

The draft read:
"Spain is administratively divided into 17 ACs and the 2 autonomous cities of Ceuta and Melilla. The ACs, **considered to be "federal states,"** are equivalent in their responsibilities to the national government except with respect to import and export controls."

The report should read:
Spain is administratively divided into 17 ACs and the 2 autonomous cities of Ceuta and Melilla. The ACs, are responsible to official controls except with respect to import and export controls."

- Page 6:

In the paragraph :"*Each year the CCA and ACs schedule training activities for the OVs. The FSIS auditor observed that the inspection staffing levels at audited establishments met the requirements of provisions of Royal Decrees 195/1998 and 118/1998*": the Royal Decrees mentioned do not exist. We cannot identify which requirements are referring.