



JUN 25 2013

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Dear Dr. Gonzalez:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Spain's meat inspection system from April 17 through May 3, 2012. You were invited to provide comments regarding the information in the draft final audit report. No comments were received from the government of Spain within 60 days. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

Sincerely,

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

JUN 25 2013

FINAL REPORT OF AN AUDIT CONDUCTED IN  
SPAIN  
APRIL 17 THROUGH MAY 3, 2012

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

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This audit report describes the outcome of an on-site ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from April 17 through May 3, 2012, to determine if Spain's food safety inspection system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled.

The focus of the audit was on the ability of the Central Competent Authority (CCA) to regulate red meat products production. The audit scope included the CCA headquarters, two Autonomous Communities (ACs), three local inspection offices including one swine slaughter establishment and two meat processing facilities, and one government microbiology laboratory. Determinations concerning the effectiveness of Spain's meat inspection system focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

The audit outcome demonstrated that the CCA was able to meet the requirements for the following equivalence components: (1), (2), (3), and (5). However, findings of systemic impact were identified within the equivalence components for (4) Hazard Analysis and Critical Control Point System (HACCP) and (6) Microbiological Testing Programs which are discussed in the body of this report and summarized as follows:

- The CCA had not adequately evaluated each establishment's HACCP plan's decision making documents for rationale and adequacy of establishment's RTE control programs within the context of each establishment's RTE hazard analysis for control of *Listeria monocytogenes* (*Lm*).
- The CCA had not adequately evaluated the verification of establishments' microbiological RTE sampling and testing programs, including an assessment of each establishment's testing methodology to ensure that establishments testing protocols for RTE product, food contact surfaces or environmental samples were fit for purpose.
- The CCA's current RTE verification sampling program is solely based on the official sampling of the finished product and does not include on-going verification sampling of food contact surface (FCS) or environmental (non food-contact surface/NFCS) testing.
- The CCA's action plan related to positive results for *Salmonella* or *Lm* testing in RTE product is limited only to official product sampling conducted at the central level. The action plan does consider positive test results related to product or food contact surface testing of the AC's domestic sampling program, or food contact surface testing during an individual establishment's own sampling program.

Spain has implemented a revised official verification RTE sampling program by collecting official FCS and NFCS samples since July 2012. Spain also implemented a single microbiological criteria based on zero tolerance for *Lm* in products or facilities and prohibition to export or reprocess any batch of production destined to the U.S. that has tested positive or has been produced on a FCS contaminated with *Lm*. FSIS will continue to verify the adequacy of the implemented corrective actions through its ongoing verification methodology and/or conducting an additional on-site audit.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AC	Autonomous Community
CCA	Central Competent Authority (Ministerio de Sanidad, Servicios Sociales e Igualdad)
CFR	Code of Federal Regulations
DGSPCI	General Directorate of Public Health, Quality, and Innovation
<i>E. coli</i>	<i>Escherichia coli</i>
EU	European Union
FCS	Food Contact Surface
FSIS	Food Safety and Inspection Service
IAS	International Audit Staff
<i>Lm</i>	<i>Listeria monocytogenes</i>
MSSSI	Ministerio de Sanidad, Servicios Sociales e Igualdad (CCA)
POE	Port of Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
Ready-to-Eat	RTE
<i>Salmonella</i>	<i>Salmonella</i> species
SGSE	General Sub directorate for Foreign Health
SRT	Self Reporting Tool
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
OV	Official Veterinarian
U. S.	The United States of America

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Spain's meat inspection system from April 17 through May 3, 2012.

The audit began with an entrance meeting held on April 17, 2012, in Madrid with the participation of representatives from the Central Competent Authority (CCA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS). The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA.

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

The audit objective was to verify that Spain's food safety system governing meat continues to be equivalent to that of the United States of America (U.S.), with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

In pursuit of this objective, FSIS conducted an analysis of information provided by Spain in the FSIS document entitled Self Reporting Tool (SRT- 2009 version), U.S.'s port-of-entry (POE) testing results, other data collected by FSIS and findings reported from on-site audits conducted in the last three years, prior to conducting this audit.

FSIS determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical residues control programs, and (6) Microbiological testing programs.

The administrative functions of the system were reviewed at CCA headquarters in Madrid, two Autonomous Communities (ACs), and three local inspection offices. During the review, the FSIS auditor evaluated the implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended.

The review of the administrative functions of the local inspection offices was conducted as part of the establishment review. One swine slaughter and two swine processing establishments were selected from a total of 15 eligible establishments currently certified to export meat products to the U.S. During the establishments' review, attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, and how the CCA provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

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

Sectors Visited During the Audit		No. Sites	Locations
Competent Authority Offices	Central	1	Madrid
	Autonomous Community	2	Catalonia and Andalucía
	Local	3	Calamocha, Pozoblanco, and Girona
Microbiology Laboratory		1	Centro Nacional De Alimentacion, Madrid
Slaughter Establishment		1	<ul style="list-style-type: none"> <li>Est. 28, Sociedad Cooperativa Ganadera Valle de Los Pedroches (COVAP) (swine)</li> </ul>
Processing Establishments		2	<ul style="list-style-type: none"> <li>Est. 26, Comercial Logistica de Calamocha, S.A. (swine)</li> <li>Est. 30, Pernils Llemená, S.A. (swine)</li> </ul>

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was conducted 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 Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

The audit standards included all applicable legislation and procedures determined to be equivalent by FSIS. Spain has equivalence determinations in place for the following:

- Testing for *Salmonellae* using PEE/LSPV/012
- Testing for *Enterobacteriaceae* and Total Viable Count *in lieu of testing* for generic *E. coli*
- EN 45001 - laboratory quality control standards
- PNTCNA IB023 method for species testing
- CAN/AESA-BA001-02 *Listeria monocytogenes* method
- CAN-AESA *Salmonella* method

### 4. BACKGROUND

The FSIS' previous routine on-going equivalence verification audit of Spain's food safety and inspection system was concluded in February 2010. Based on the 2010 audit, the CCA had the legal authority and the responsibility to enforce all applicable meat inspection system laws and regulations governing Spain and third country requirements. However, the audit concluded that

these requirements were not consistently applied throughout the food safety system, which resulted in the CCA initiating an enforcement action, Notice of Intent to Delist or NOID, in one of the five establishments audited. During that audit, the CCA proffered corrective actions, which were complemented a few months later with inspection verification and supporting documentation. The analysis of these documents led FSIS to conclude that Spain continues to operate a food safety inspection system equivalent to that of the United States.

During the current on-site audit, the auditor's review of the CCA's corrective action and verification documents demonstrated effectiveness of the corrective actions and preventive measures proffered by the CCA for the 2010 audit findings.

Spain is eligible to export processed pork meat products to the U.S. Spain exported 2,074,307 pounds of processed pork products in 2011. A total of 832,520 pounds were re-inspected by FSIS at POE in which 10,954 pounds was rejected because of transportation damage, labeling/shipping marks defects, and two lots because of *Listeria monocytogenes* (*Lm*) violations.

A review of Spain's POE violations since the last FSIS audit demonstrated that Spain had four POE violations concerning *Lm* as follows:

- Est. 16, sampling date of 04/01/2010, dry-cured pork loin
- Est. 23, sampling date of 04/06/2010, dry-cured whole muscle ready-to-eat boneless Iberico de Bellota ham
- Est. 26, sampling date of 05/26/2011, dry-cured whole muscle ready-to-eat boneless Noel Serrano ham
- Est. 26, sampling date of 05/26/2011, dry-cured whole muscle ready-to-eat boneless Iberico ham

As a result of these POE violations, FSIS scheduled this ongoing equivalence verification audit with special emphasis on Spain's regulatory oversight governing RTE products exported to the U.S. The evaluation of Spain's RTE program included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and on-site reviews and observations made by the FSIS auditor during the audit of government offices, establishments, and the reference microbiology laboratory. FSIS' audit identified specific findings for two equivalence components of HACCP systems (C4) and Microbiological Testing Programs (C6) which are discussed in the related sections of this report.

The FSIS final audit reports for Spain's meat inspection system are available on the FSIS' website at:

[http://www.fsis.usda.gov/Regulations\\_&Policies/ForeignAuditReports/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/ForeignAuditReports/index.asp)

## 5. GOVERNMENT OVERSIGHT

This audit focused on the CCA's performance within six equivalence components upon which system equivalence is based. The first of the six components that FSIS reviewed was Government Oversight. 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 (2009 version) 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, Ministry of Health, Social Services and Equality (MSSSI) and Ministry of Agriculture, Food and Environment (MAGRAMA). The chain of command begins with the MSSSI, the Central Competent Authority (hereinafter called the Ministry of Health or CCA), which is responsible in general for matters of food safety, and in particular for the direct authorization and supervision of the export establishments, developing and implementing controls over the products they produce, and ensuring that the internal procedures in the establishments are safe from a health perspective. 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 from the public health point of view. 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. Therefore, there are some issues which both ministries are competent for (i.e. foods of animal origin, drugs, etc.).

There is also a Spanish Agency of Consumers Affairs, Food Safety and Nutrition (AECOSA) 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 regarding 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, but it has no food inspection responsibilities.

Spain is divided into 17 Autonomous Communities (ACs). The ACs are considered to be "federal states," equivalent in their responsibilities to the national government. There was a decentralization of government functions in the 1980s, as a result of which the central government transferred to the ACs the responsibilities for regulation and enforcement in the field of public health, including food control; the central government, however, maintains exclusive responsibilities for some aspects of public health, including import and export controls at Spain's borders.

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 U.S.-certified establishments. At the moment, seven ACs contained U.S.-certified establishments.

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) and its General Sub directorate for Foreign Health (SGSE). 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 analyzes of meat products exported to the U.S.

The CCA has a written protocol titled “General Procedures on Export of Meat and Products to the USA” that describes the procedures that establishment operators should follow to obtain approval from SGSE to become certified for export and the actions taken by government officials at each step of the approval process. The CCA conducts the initial determinations of establishments that wish to become eligible to export to the United States and the CCA has the sole authority to grant final certification of a new establishment or to permit an existing US-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 have been scheduled coordination meetings (reuniones de coordinacion periodicas), three to four times per year, between the CCA and the ACs. The FSIS auditor reviewed coordination meeting notes at Catalonia and Andalucía Autonomous Communities. The meeting notes included such topics that 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 instructions 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 implemented a standard format for documenting inspection verification and enforcement activities through a computer based application known as Quaestor. On a daily basis, in-plant inspection personnel enter the results of their routine inspection verification or enforcement activities into the computer application. The inspector’s verification results are available for review by both ACs and the CCA officials.

Quaestor is managed and maintained by the CCA and is being used for gathering inspection data and performing trend and risk analysis for the U.S. certified establishments. This computer program has created a uniform database of information which included inspection forms and procedures to be used by the official veterinarian assigned to the U.S. certified establishments throughout the country. This program has separate tabs for Sanitation SOP, HACCP, product and process control, pre-shipment reviews, equipment, and hygiene controls regarding operations and personnel. The inspection personnel demonstrated the availability and application of Quaestor by accessing requested information by the FSIS auditor. This information included an overview of the last 90 days in-plant inspection verification of HACCP, sanitation, and

enforcement activities. In addition, ACs' supervisors 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 ACs' supervisors have provided adequate oversight to ensure the proper implementation of the program.

The FSIS auditor observed that official verification and inspection activities were conducted at audited certified establishments in accordance with uniform instructions disseminated, through Quaestor application, from the CCA to the field personnel in the manual of inspection procedures "Procedimientos Inspeccion Establecimientos Autorizados EEUU".

FSIS verified that ACs inspection personnel were familiar with technical and administrative application of Quaestor. FSIS observed that the resident veterinarians at the audited establishments and ACs supervisors could access the system from their establishments and were proficient in gathering and filtering data to generate examples of sanitation and HACCP related activities. The program allows the CCA and ACs to analyze the information gathered by the inspection personnel at the U.S. eligible establishments. The CCA and ACs inspection personnel analyze this information to detect trends that may lead to new policy development, assess effectiveness of existing policies, and determine training needs for inspection personnel. The FSIS auditor reviewed the CCA's assessment of sanitation and HACCP verification activities and the number of non-compliances related to each activity as part of CCA's risk assessment for each establishment for determining the frequency of periodic supervisory reviews. No concern arose as a result of this review.

The CCA and ACs also assessed the implementation of inspection requirements, through review of records generated in Quaestor, by in-plant inspection personnel in performing the assigned duties by reviewing the contents of the Quaestor. This is in addition to on-site evaluation of inspection personnel to determine their knowledge, skills, and abilities for conducting assigned responsibilities.

The auditor reviewed and verified the application of periodic supervisory reviews at the CCA headquarter, two ACs, and three 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 (including SPS requirements), 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), and compliance and economic control (including export certificate, equivalency status), HACCP and sanitation requirements. FSIS also verified that upon conclusion of the supervisory review, ACs 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 U.S. The ACs recruits OV from state veterinary universities and provides required general trainings. 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 U.S. certified establishments. The ACs are considered to be “federal states,” equivalent in their responsibilities to the national government.

The FSIS auditor reviewed the CCA and two audited ACs official training records for 2010 and 2011. This review indicated that in-plant inspection personnel have successfully completed training that includes HACCP, SSOP, fecal contamination examination, inspection verification, and an RTE overview course that addressed a review of 9 CFR Part 430, Directive 10240, Spain’s national procedures for RTE sampling, and measures to be taken in response to a positive results in RTE product.

Each year the CCA and ACs schedule’s training activities for the OVs. The AC is the party responsible for overseeing the activities of the OVs in certified establishments. 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.

At the swine slaughter establishment, the auditor reviewed *Salmonella sampling* methodology on swine carcasses and directly observed the sample collection process on carcasses, handling, and shipping of official samples to accredited government laboratories. This process was under the oversight of the CCA and ACs and in accordance with FSIS requirements.

The FSIS auditor verified that the CCA provides laboratory oversight. This was determined by conducting a verification audit at the central microbiology laboratory. Spain’s laboratories that are part of the technical support of the CCA inspection system maintain accreditation through Spanish accreditation body (ENAC). This aspect of the system is further described in the Microbiological and Chemical Residue Program components portions of this report. 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.

In conclusion, Spain’s meat inspection system is organized and administered by the national government and provides standards equivalent to those of the Federal system of meat inspection in the United States. Therefore, this component of the system continues to meet equivalence criteria. However, FSIS’ audit identified specific findings concerning RTE control program for two equivalence components of HACCP systems (C4) and Microbiological Testing Programs (C6) which have implications within all other components including the Government Oversight component. The audit findings for (C4) and (C6) are discussed in details in related sections of this report. The CCA must ensure that the revised RTE program, as it was proposed during the exit meeting, is verified for effectiveness and communicated through the chain of command for proper implementation. As part of on-going equivalence verification, FSIS will further verify this by requesting inspection information such as periodic supervisory reviews for RTE producing establishments to determine that the revised program has been implemented through out the inspection system.

## 6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the

regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of processed meat inspection organized and maintained in the U.S.

The 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 supporting documentation.

This evaluation demonstrated that the Spain's inspection system has statutory authority to deliver inspection to all certified establishments, described in Regulation (EC) 852, 853, 854, and 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. Furthermore, the CCA has regulatory requirements that require that official inspection personnel, laboratories, and establishments meet the requirements of importing countries.

During the on-site audit of one swine slaughter establishment, the FSIS auditor observed the function of inspection personnel while performing ante-mortem inspection activities at the holding pens. The official veterinarian conducted ante-mortem inspection on the day of slaughter by reviewing the in-coming registration and identification document with each load/truck and observing all swine at rest and in motion from both side in designated holding pens in order to determine whether they are fit for slaughter. There was a separate pen 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 if held overnight then feed would be provided. The auditor concluded that the implementation of the ante-mortem inspection was in compliance with EU and Spain regulations. This also met applicable portions of FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection".

The FSIS auditor assessed technical aspects of post-mortem inspection at one U.S. certified swine slaughter establishment. The auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. All inspection personnel in U.S. eligible establishments were veterinarians. These veterinarians were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the 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 EU regulations which have been recognized as equivalent to FSIS requirements. This also met applicable portions of FSIS Directive 6100.2 "Post-Mortem Livestock Inspection". The design of the post-mortem inspection stations including proper lighting and the number of on-line inspectors also met Spain's requirements.

The FSIS 2010 final audit report noted that all inspection personnel at the audited slaughter establishment were performing only on-line inspection activities. Therefore, off-line inspection verification activities such as sanitation and HACCP verifications were not fully implemented. In response to this observation, the CCA has added an off-line veterinarian to all the U.S. certified slaughter establishments. During the current audit, the FSIS auditor also observed and

verified the functions of the off-line veterinarian who has an in-plant supervisory role to ensure that all applicable regulations are being implemented.

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 U.S. 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 the in-plant inspection personnel on a daily basis as well as the CCA and ACs supervisory review records. Spain has adopted FSIS Directive 5000.1 and its procedures concerning issuing non-compliance report (NR). 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. The FSIS auditor reviewed a sample of open and closed NRs issued from January 1, 2012 to the day of the audit for 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 FSIS auditor also verified that all the non-compliances reported during the last FSIS audit were adequately addressed and corrected. The conditions in the plant 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. Therefore, this component of the system continues to meet equivalence criteria. However, FSIS' audit identified specific findings concerning RTE control program for two equivalence components of HACCP systems (C4) and Microbiological Testing Programs (C6) which compromises the ability of the CCA to effectively verify the consistent production of wholesome and unadulterated meat products intended for export to the U.S. These findings are discussed in details in related sections of this report.

## 7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. The evaluation of this component included a review and analysis of Spain's' documentation, including regulations (EC) 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 Regulation (EC) No 852/2004 - Article 4 and Annex II, Chapter V, Regulation (EC) No 853/2004- Annex

III, Section I, Section VI, Regulation (EC) No 854/2004- Article 4, Regulation (EC) 178/2002, Articles 6, 7, 53, 54, 55, 56, 57, 58, and 60, Regulation (EC) 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 sanitation programs sufficient to prevent direct product contamination and the creation of insanitary conditions.

The CCA demonstrated that it enforces aforementioned EU sanitary regulations which have been 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 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 RTE production areas to demonstrate the adequacy of the sanitation procedures. The in-plant inspectors entered sanitation verification data into the Quaestor program which would be analyzed to detect trends that may lead to revision of sanitary procedures.

During the assessment of this component, the FSIS auditor reviewed the design and implementation of sanitation programs at the audited establishments. The FSIS auditor observed the in-plant inspector 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 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 audited establishments. These verification activities included direct observation of operational process and review of establishment's operational records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection's verification records for the same time period. FSIS auditor noted that the inspection and establishment records were mirroring the actual sanitary condition of the establishment. The audited establishments did maintain sanitation records sufficient to document the implementation and monitoring the SSOP and any corrective actions taken. The establishment employee(s) specified as being responsible for the implementation and monitoring of the SSOP procedures authenticated these records with initials or signatures and the date. No concern arose as the result of this review.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS demonstrated that the CCA inspection system provides requirements equivalent to those of FSIS system for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. In-plant veterinary officials and the CCA and ACs supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions. Therefore, this component of the system continues to meet equivalence criteria. However, there are concerns that the CCA must address related to Spain's

recent POE *Lm* violations and the positive *Lm* results in the post-lethality processing environment in the exporting establishments. FSIS expects that the CCA should continue effective verification of the sanitation program in control of *Lm* in the post-lethality processing environment to ensure that RTE producing establishments have effectively implemented their sanitation and prerequisite programs to destroy *Lm*, and *Salmonella* and to prevent re-contamination with pathogens, particularly *Lm*, in the post-lethality processing environment. FSIS will further verify this through its on-going equivalence methodology.

## 8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components reviewed by FSIS was HACCP systems. The inspection system must require that each official establishment develop, implement and maintain a HACCP plan. 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 three of the certified establishments.

The FSIS auditor reviewed the CCA's document "General Procedures of Export of Meat and/or Meat Products to the United States" that 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. HACCP related document review 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 enforced FSIS' 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 included the evaluation of written HACCP plans and its contents, record review and hands-on inspection of monitoring and verification activities, and implementation of corrective actions when there is a deviation from the critical limits. The in-plant inspectors entered the HACCP related data into the Quaestor program.

Documents reviewed by the FSIS auditor included regulatory standards, training materials, and regulatory guidelines issued by the CCA. FSIS also assessed the adequacy of 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 U.S. certified establishments, regulatory requirements for the development, implementation and maintenance of HACCP programs as set forth in the FSIS regulations. The official inspection verification activities included an assessment of the design and execution of the establishment's HACCP programs including monitoring, corrective actions, record keeping, and verification activities.

The FSIS auditor reviewed slaughter establishment's records for zero tolerance CCP generated within the last three months. In addition, FSIS auditor reviewed the in plant inspection's zero tolerance CCP verification records for visible ingesta, feces and milk on swine carcasses. Both

inspection and establishment monitoring or verification records documented a few deviations from the critical limits. No trends were detected as the result of these document reviews. Furthermore, FSIS auditor stood at zero tolerance CCP location and not only observed the inspection personnel conducting HACCP hands-on verification activities at this CCP but also made a direct examination of swine carcasses. No deviation from the critical limits was observed by the inspection personnel or FSIS auditor. The CCP location met Spain's requirement including the adequate illumination for proper examination.

The review of the establishment's corrective actions in response to deviation from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance with 9 CFR part 417, were addressed by audited slaughter establishment and verified by the inspection personnel. The corrective action included:

- 1) identifying and eliminating the cause of the deviation from a critical limit. The causes was determined be an equipment malfunction or employee's error;
- 2) bringing the CCP under control after the corrective action is taken. This may achieve by increasing the monitoring frequency by establishment personnel. The inspection may increase its verification frequency to ensure that the establishment proposed corrective actions are sufficient;
- 3) applying measures to prevent recurrence such as equipment adjustment and employee's training; and
- 4) assurance no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce. This included an examination of all affected swine carcasses back to the last acceptable check by the establishment.

The FSIS auditor observed that the audited establishments were testing for *Lm* in the finished product, food contact surfaces (FCS) and processing environment as mandated by the CCA. The RTE producing establishments are ultimately responsible for ensuring that sampling protocols and testing methods meet the needs of their food safety programs. At the same time, the CCA and its inspection personnel are responsible to assess decision making documents for rationale and to verify adequacy of food safety programs within the context of each establishment hazard analysis and HACCP plan. However, the inspection officials did not verify that the analytical microbiology methods, used by private microbiology laboratories contracted by certified establishments to test the finished product, FCS or environmental samples matrices, were validated analytical methods that would fit for the purpose. As a result, FSIS auditor noted that the CCA had not adequately evaluated: 1) the establishment's HACCP plan's decision making documents for rationale and adequacy of establishment's RTE control programs within the context of each establishment's RTE hazard analysis for control of *Lm*, and 2) the verification of establishments' microbiological sampling and testing programs including an assessment of each establishment's RTE testing methodology and its implementation. The CCA proposed corrective actions to address the noted concerns. FSIS will further verify the CCA proposed corrective actions and analyze its effectiveness through its on-going equivalence methodology.

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 conclusion, the results of the assessment of the HACCP programs demonstrated that Spain's inspection system provides requirements equivalent to those of FSIS regulatory requirements. In-plant veterinary officials and ACs supervisors monitor, verify and enforce the implementation of most of the regulatory requirements in the certified establishments. However, there are HACCP related concerns that the CCA must address regarding Spain's RTE control program and in particular, the recent *Lm* violations in the U.S. POE import sampling and the positive *Lm* results from testing by Spain in the post-lethality processing environment in the exporting establishments. FSIS expects that the CCA's proposed changes in the current RTE control program should be reflected in both the CCA's on-going HACCP verification activities and in particular in ACs periodic supervisory HACCP reviews to ensure the effective implementation of the HACCP verification program.

## 9. CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth of the six equivalence components. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. In addition, the CCA must provide a description of the actions taken to deal with unsafe residues as they occur as well as measures to deter recurrence. The CCA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data. Spain's system met the criteria for this component.

Spain's national residue program and its implementation and results were reviewed by the FSIS's headquarter experts prior to the audit. This was an in-depth review and analysis of Spain's residue program documentation submitted to FSIS as support for the responses provided in the SRT (2009 version). In addition, a review of the FSIS's Automated Import Inspection System (AIIS) database indicated that there have not been any chemical residue related POE violations since the last FSIS audit.

During the on-site audit, FSIS reviewed Spain's chemical residue control programs at the CCA's headquarter, one AC office, and one certified slaughter establishment to verify the implementation and enforcement of the regulatory requirements. An on-site review of residue laboratory was not in the scope of this audit. 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*. The CCA official control measures and enforcement actions are defined in Chapter IV which includes the CCA responsibilities to obtain information when positive or violative results occur, to identify the animal and farm of origin, to investigate the cause of the violation at the farm, to safeguard the public health by product disposition, to intensify the checks on the animals and products from the farm, and to impose criminal or administrative penalties against any person who is responsible. This directive has been recognized as equivalent by FSIS. The FSIS review indicated that Spain's national residue testing program for 2012 was being followed and was on schedule.

In conclusion, Spain's meat inspection system has regulatory requirements for a chemical residue control program that is organized and administered by the national government in

accordance with EU requirements and meets FSIS equivalence requirements. Therefore, this component of the system continues to meet equivalence criteria.

## 10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to microbiological testing program organized and administered by the national government to verify that products destined for export to the U.S. 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 (2009 version) 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 Spanish accreditation body (ENAC). These audits have reported a few non-conformances which were addressed and corrected by the laboratory's quality control. This laboratory is ISO 17025 accredited in accordance with ENAC standards.

FSIS reviewed the CCA's 2011 annual report concerning its oversight responsibility and its role on laboratory inspection. Based on this report, the CCA visited two microbiological laboratories conducting verification testing for *Salmonella* in raw products (slaughter establishments) and *Salmonella* and *L. monocytogenes* in finished product (RTE establishments). In both laboratories, the CCA concluded compliance with equivalence requirements including application of FSIS approved or recognized equivalent analytical methodology. No concerns arose as a result of these reviews.

RTE control program records were reviewed at CCA headquarters and two establishments producing RTE product, of which one presented prior POE violations for *Lm*. This review indicated that the CCA took appropriate enforcement actions in response to these violations, including suspension of U.S. export certification activities and initiation of an official verification action plan in accordance with the CCA's *Lm* control program. The establishment remained suspended until all noncompliances were addressed in accordance to Spain's requirements.

While on-site, the auditor verified that the CCA had adopted FSIS regulatory requirements related to the control of *Lm* in the post-lethality environment as outlined in 9 CFR Part 430. The CCA has administered a regulatory microbiological verification program which included additional RTE products sampling at those meat processing establishments which are eligible for export to the U.S. This program differs from the national microbiological verification program administered by the ACs for products that are destined for the domestic or the European Union (EU) market. The CCA does not have a direct responsibility or oversight for the domestic/EU market production or ACs sampling programs. In most cases, operations related to production of

RTE product for either export to the U.S. or other markets are using common equipment at different time in an U.S. eligible establishment. The auditor noted that it was possible for U.S.-eligible establishments to receive product, for further processing, from other U.S.-eligible establishments as well as those which are not, the latter of which are operating under different RTE control program standards. This situation caused concern as it was further noted that the CCA's RTE verification sampling program of the U.S. certified establishments is based solely on the official sampling of finished product and does not include an on-going verification sampling of food contact surface (FCS) or environmental (non-food contact surface/NFCS) testing. In addition, the CCA's verification activities do not take into consideration the results of the AC's internal sampling program conducted on product destined for the domestic/EU market. This practice may have a potential impact on the U.S. certified establishments production by two means. First, considering the fact that the same facility is being used for producing RTE product for both the U.S. and domestic/EU markets, the positive result detection of *Lm* by the AC's domestic RTE sampling program could be used to further evaluate the overall effectiveness of the sanitary control measures in the U.S. eligible RTE producing establishments. Second, the AC's sampling results may also assist the CCA in its on-going risk assessment and potential adoption of additional verification activities or elevated enforcement actions related to control of *Lm* and *Salmonella* programs in the U.S. eligible establishments.

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* and/or *Lm* are detected positive in RTE products. However, the auditor noted that this action plan is only applicable when there is a positive result for the CCA's official finished product sampling and does not apply when a positive test result occurs during:

- Product testing during the AC's internal sampling/testing program (for EU/domestic market)
- Food contact surface testing during the AC's internal sampling program (for EU/domestic market)
- Food contact surface testing during the establishment's verification sampling program (self control testing by establishment)

Based on FSIS requirements which are adopted by Spain, RTE product is adulterated if it contains *Lm*, or if it comes into direct contact with a food contact surface that is contaminated with *Lm*. Therefore, FSIS expects that the CCA initiates enforcement actions for positive sample results for the aforementioned scenarios.

Based upon these findings, in association with the recent POE violations, FSIS concluded that Spain's inspection system did not demonstrate the same level of protection as that provided by the U.S. system to control pathogenic microorganisms typically associated with RTE products. A summary of the most significant concerns identified during the audit include the lack of:

- a) CCA enforcement actions related to positive FCS sample results obtained by ACs or individual establishments,
- b) CCA verification activities, including verification sampling of food contact surface or environment to ensure the effectiveness of the establishments' control measures in controlling *Lm* in the post-lethality processing environment,
- c) information sharing

between ACs and the CCA within those establishment operating under two standards (U.S. and domestic).

## 11. EXIT MEETING

An exit meeting was held on May 3, 2012, in Madrid, with the Spanish officials from the CCA and representatives of several ACs. At this meeting, the FSIS auditor presented the preliminary findings of the audit.

## 12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

FSIS concluded that the CCA was able to meet the requirements for the equivalence components of (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, and (5) Chemical Residue Programs. However, findings of systemic impact were identified within the equivalence components of (4) Hazard Analysis and Critical Control Point (HACCP) Systems and (6) Microbiological Testing Programs which have an impact on all aforementioned components. FSIS needs to further evaluate the effectiveness of the CCA proposed corrective actions through its on-going equivalence verification methodology before making its final conclusion for these components.

The FSIS has concerns that the CCA has not implemented adequate enforcement actions for the positive FCS sample results or initiated FCS/environmental sampling verification to ensure the effectiveness of the establishment's RTE control programs in the post-lethality processing environment. Given the positive *Lm* results in both certified establishments and U.S. POE imported RTE product sampling, Spain must provide supporting documentation to justify its current RTE control program or to adopt new measures that prevent product adulteration by *Lm*.

In order to demonstrate an equivalent inspection system, the CCA must provide comprehensive corrective actions addressing specific audit findings outlined in the report. In addition, FSIS's on-going verification methodology needs further evidence of Spain's implementation of the following commitments, indicating that:

- all data gathered from RTE related testing for other markets including domestic or exporting to the third countries would be evaluated by the CCA in cases where it may affect RTE programs for U.S. products
- the revised RTE program is verified for effectiveness and communicated through the chain-of-command for proper implementation
- the CCA's proposed changes in the current RTE control program would be reflected in both the CCA's on-going verification activities and its periodic supervisory reviews to ensure the effectiveness of the modified RTE control program
- the CCA ensures that RTE producing establishments have effectively implemented their sanitation and prerequisite programs to destroy *Lm*, and *Salmonella* and to prevent re-contamination with pathogens, particularly *Lm*, in the post-lethality handling environment

FSIS audit findings also indicated a potential need to modify the frequency or methodology of the CCA's periodic supervisory reviews since the audit findings were not identified or addressed by the CCA prior to the FSIS audit. FSIS is seeking supporting documentation for the CCA decision on this issue.

### 13. PROFFERED CORRECTIVE ACTIONS

At the end of the exit meeting on May 3, 2012, the CCA submitted its proposed draft action plan. The FSIS received an updated version of this action plan on July 17, 2012, that further explains the CCA proffered corrective actions in the design and execution of the food safety inspection system concerning *Lm* control programs. The CCA has provided the following corrective actions to FSIS's audit findings:

- The implementation of official sampling of food contact surfaces and non food contact surfaces as the result of the reassessment of the official RTE sampling program. This program started on July 16, 2012.
- The consideration of the Autonomous Communities RTE sampling results for products intended for the EU market.
- The participation of official inspectors and supervisors on July 11 and 12, 2012, in a 15 hours training course focused on verification of the RTE production to strengthen the implementation of the aforementioned instructions.
- The prohibition to export or reprocess any batch of production destined to the U.S. that has tested positive or has been produced on a food contact surface contaminated with *Lm*. This includes both official and establishment self-control sampling results.
- The implementation of a single microbiological criteria based on zero tolerance for *Lm* in products or facilities and to take corrective actions for positive results regardless of the destination of the product.
- The application of the sponge or towel by establishments in sampling of FCS and NFCS in the post-lethality processing environment to increase the sampling effectiveness. These samples must be analyzed by validated analytical methods that have the recognition of an internationally recognized organization and include pre-enrichment.

The CCA informed FSIS that it has implemented its proposed corrective actions. The CCA has reassessed and implemented its revised official RTE sampling program including official sampling of FCS and NFCS in all 14 U.S. eligible establishments. The CCA implemented a single microbiological criteria based on zero tolerance for *Lm* in products or facilities and prohibition to export or reprocess any batch of production destined to the U.S. that has tested positive or has been produced on a FCS contaminated with *Lm*. The CCA also arranged a training course "Verification of the RTE Production" with participation of 24 official inspectors from the CCA and seven ACs involved with the U.S. eligible establishments.

FSIS will continue to verify Spain's RTE official control and the adequacy of the implemented corrective actions through its ongoing verification methodology and/or conducting an additional on-site audit.

Nader Memarian, DVM  
Senior Program Auditor



#### 14. ATTACHMENTS TO THE AUDIT REPORT

##### Individual Foreign Establishment Audit Checklists

No Foreign Country Response to Draft Final Audit Report was provided by June 24, 2013, when this report was finalized.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Commercial Logistica De Calamochas S.A. Calamocha	2. AUDIT DATE April 19, 2012	3. ESTABLISHMENT NO. 26	4. NAME OF COUNTRY Spain
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

Est. 26 - Swine Processing Operation

- The CCA has adopted FSIS regulatory requirements related to the control of *Lm* in the post-lethality environment as outlined in 9 CFR Part 430
- The FSIS' equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat products (RTE) control program states that: A) On an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective, and B) The U.S. eligible establishments employ an analytical testing method for *Lm*, and *Salmonella* for RTE products, and *Lm* on product contact surfaces, and environmental surfaces that (1) is scientifically validated and has been approved or adopted by an internationally recognized organization, (2) includes an enrichment period that allows for the recovery and resuscitation of any sub-lethally injured cells and also allows for the outgrowth of very low numbers of *Lm* to levels that be detected by the test method, and (3) the sensitivity of the method is equal to or better than the FSIS method.

51: Audit Findings concerning CCA's Enforcement:

- 1) The CCA's RTE verification sampling program of the U.S. certified establishments was based solely on the official sampling of finished product and did not include an on-going verification sampling of food contact surface (FCS) or environmental (non-food contact surface/NFCS).
- 2) The CCA had not adequately verified that the analytical microbiology methods, used by private microbiology laboratories contracted by this certified establishment to test the finished product, FCS or environmental samples matrices, were validated analytical methods that would fit for the purpose.
- 3) The CCA had not adequately evaluated the establishment's HACCP plan's decision making documents for rationale and adequacy of establishment's RTE control programs within the context of establishment's RTE hazard analysis for control of *Lm*.

61. NAME OF AUDITOR  
Nader Memarian. DVM

62. AUDITOR SIGNATURE AND DATE

 4-19-12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sociedad Cooperativa Valle De Los Pedroches Pozoblanco	2. AUDIT DATE April 26, 2012	3. ESTABLISHMENT NO. 28	4. NAME OF COUNTRY Spain
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 28 – Swine Slaughter Operation

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

61. NAME OF AUDITOR  
Nader Memarian. DVM

62. AUDITOR SIGNATURE AND DATE

 4-26-12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Pernils Ilemens S.A. Girona	2. AUDIT DATE April 24, 2012	3. ESTABLISHMENT NO. 30	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. Nader Memarian		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

- The CCA has adopted FSIS regulatory requirements related to the control of *Lm* in the post-lethality environment as outlined in 9 CFR Part 430
- The FSIS' equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat products (RTE) control program states that: A) On an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective, and B) The U.S. eligible establishments employ an analytical testing method for *Lm*, and *Salmonella* for RTE products, and *Lm* on product contact surfaces, and environmental surfaces that (1) is scientifically validated and has been approved or adopted by an internationally recognized organization, (2) includes an enrichment period that allows for the recovery and resuscitation of any sub-lethally injured cells and also allows for the outgrowth of very low numbers of *Lm* to levels that be detected by the test method, and (3) the sensitivity of the method is equal to or better than the FSIS method.

51: Audit Findings concerning CCA's Enforcement:

- 1) The CCA's RTE verification sampling program of the U.S. certified establishments was based solely on the official sampling of finished product and did not include an on-going verification sampling of food contact surface (FCS) or environmental (non-food contact surface/NFCS).
- 2) The CCA had not adequately verified that the analytical microbiology methods, used by private microbiology laboratories contracted by this certified establishment to test the finished product, FCS or environmental samples matrices, were validated analytical methods that would fit for the purpose.
- 3) The CCA had not adequately evaluated the establishment's HACCP plan's decision making documents for rationale and adequacy of establishment's RTE control programs within the context of establishment's RTE hazard analysis for control of *Lm*.

61. NAME OF AUDITOR  
Nader Memarian. DVM

62. AUDITOR SIGNATURE AND DATE

*Nader Memarian* 4-24-12