USDA

United States Department of Agriculture

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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
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Dear Dr. Vaquer,

The FSIS onsite audit conducted from September 27 through October 19, 2017, supports that Spain's inspection system for raw and processed pork products continues to remain equivalent to that of the United States. 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 any questions regarding the FSIS audit report, please contact us at (202) 708-9543, or by electronic mail at internationalcoordination@fsis.usda.gov.

Sincerely,

Todd Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

SPAIN

SEPTEMBER 27 TO OCTOBER 19, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

March 26, 2018

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 27 to October 19, 2017. The purpose of the audit was to determine whether Spain's food safety system governing slaughtered and processed meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Spain currently exports the following categories of pork products to the United States: 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: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The Central Competent Authority (CCA) did not adequately verify that establishments met government sanitation requirements that ensure ventilation is sufficient to control condensation in order to protect product and prevent the creation of insanitary conditions. The same finding was noted during the 2015 FSIS audit. The CCA's verification efforts did not ensure that the establishments' corrective actions were effective at controlling condensation to prevent recurrence of noncompliance.

During the audit exit meeting, the CCA committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Spain's food safety system from September 27 to October 19, 2017. The audit began with an entrance meeting held on September 27, 2017 in Madrid, Spain, during which FSIS discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) - the Ministry of Health, Social Services, and Equality (MSSSI), the Ministry of Agriculture and Fisheries, Food and Environment (MAPAMA) and the FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing slaughtered and processed meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Spain is eligible to export raw and further processed pork products in the following process categories raw– intact; raw – not intact; fully cooked – not shelf stable; not heat-treated – shelf stable; and heat-treated – not fully cooked – not shelf stable pork products to the United States.

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

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA and representatives from the regional offices in Catalonia, Castilla la Mancha, La Rioja, and Valencia Comunidades Autónomas (CAs), and the local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at CCA headquarters, one CA regional office, and at six local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

Seven establishments were selected for the audit from the 24 establishments certified as eligible to export to the United States. Two conducted slaughter and processing operations. The other conducted processing only. One of the seven establishments was not audited as planned due to

safety concerns for FSIS auditors during a general citizen's strike resulting from political tensions from the Catalonia independence referendum. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety.

The FSIS auditors examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Part 327.2. Additionally, FSIS audited one government microbiological laboratory to verify the CCA's ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• MSSSI, Madrid (Madrid)
	Regional	1	• Autonomous Community Cataluña, Barcelona (Barcelona)
Laboratory		1	• Public Health Laboratory, Valencia (government)(microbiological)(Valencia)
Meat slaughter and processing establishments		2	• Establishment 33, Riudellots de la Selva, Girona (Catalonia) • Establishment 37, Corco, Barcelona (Catalonia)
Meat processing establishments		5	• Establishment 14, Torrijos, Toledo (Castilla la Mancha) • Establishment 16, Albelda de Iregua, Logroño (La Rioja) • Establishment 20, Utiel, Valencia (Valencia) • Establishment 24, El Rasillo, La Rioja (La Rioja) • Establishment 30, Sant Aniol de Finestres, Girona (Catalonia) – Not audited

The audit was undertaken to verify whether the country's food safety system was equivalent to FSIS's system in regards to specific provisions of United States' laws and regulations, in particular:

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

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

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;

- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 1099/2009;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC; and
- Council Directive 96/23/EC.

III. BACKGROUND

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Spain as low risk for classical swine fever (CSF), free of rinderpest and foot-and-mouth disease (FMD) with restrictions, free of swine vesicular disease (SVD) with restrictions, and negligible risk for bovine spongiform encephalopathy. Spain currently exports raw and further processed pork products to the United States.

From June 1, 2014 to May 31, 2017, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 36,795,377 pounds of slaughtered and processed pork products exported by Spain to the United States. Of that amount, additional types of inspections were performed on 4,709,053 pounds, of which no product was rejected due to any food safety or other reasons. FSIS' 2015 audit found that the CCA was not adequately verifying that establishments met requirements for ventilation to control contamination.

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

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

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

The FSIS auditors verified that the inspection system is organized and administered by the national government of Spain. There have been no major changes in the CCA's organizational structure since the last FSIS audit. Spain as a member of the European Union (EU), has adopted the EU legislation pertaining to food of animal origin, and has based its authority to enforce inspection laws on Regulation (EC) No. 178/2002. The EU regulations are the primary overarching laws for regulating meat inspection. Spain is responsible for ensuring that adulterated or misbranded products are not exported to the United States through their national

legislation and implementing regulations. The CCA definitions for adulterated and misbranded are based on the *Ministry Order of April 4, 1995, Technical-Sanitary Conditions and Conditions of Authorization Applicable to Establishments of Meat and Meat Products for Export to the United States of America*.

The responsibility for Spain's meat inspection control system lies with MSSSI and MAPAMA. The chain of command begins with MSSSI, the CCA, which has principal responsibility for food safety and is directly responsible for implementing import controls on all food. In particular, it has 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. MAPAMA is principally responsible for animal health, animal identification and traceability, plant health, sanitary agreements with third countries, coordination of zoosanitary and phytosanitary surveillance, control at border inspection posts, animal welfare, animal feed, and primary production of food of animal origin.

Spain is administratively divided into 17 CAs and two autonomous cities of Ceuta and Melilla. The CAs 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 CAs 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 CAs 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.

The FSIS auditors verified that the CCA maintains exclusive responsibility for implementing the general principles of health, providing direct oversight for CAs 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 CAs that contain establishments certified to export to the United States. At this time, the following nine of the 17 CAs contain establishments certified to export to the United States: Andalucía, Aragón, Castilla la Mancha, Castilla-León, Catalonia, Extremadura, La Rioja, Galicia, and Valencia.

The National Food Chain Official Control Plan (PNCOCA) is the main instrument coordinating the activities of the Servicios Veterinarios Oficiales (SVO) of animal and public health. The annual report is prepared jointly by the Spanish Agency for Consumer Affairs Food Safety and Nutrition, MAPAMA, and the Deputy Directorate General for Foreign Health, with significant input from each of the 17 CAs and the two autonomous cities of Ceuta and Melilla. The annual reports are submitted to the EC on a yearly basis. The current PNCOCA covers the years 2016-2020.

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

publication *Inspection Procedures for U.S. Approved Establishments* provides details about the responsibilities of the Directorate General for Public Health, Quality and Innovation (DGSPCI) and the CAs regarding assignments, training, and supervision of official personnel assigned to establishments certified to export to the United States. It also provides general guidance to in-plant inspection personnel on the official HACCP, Sanitation Standard Operating Procedures (Sanitation SOP), Sanitation Performance Standards (SPS), and pathogen reduction (PR) inspection tasks that they are to routinely perform at establishments certified to export to the United States.

The CCA has one central office headed by the Minister of Health. The Head of the Official Veterinary Services is the Subdirección General de Sanidad Exterior (SGSE). Within the CCA, the department with inspection and control responsibilities regarding exports and imports is the DGSPCI and its 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 CAs 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.

Royal Decree 993/2014, Procedure and Requirements of the Official Veterinary Certification for Export, states that certification and decertification falls exclusively to the central government authority and approval of establishments is governed by the *Ministry Order of April 4, 1995, Technical-Sanitary Conditions and Conditions of Authorization Applicable to Establishments of Meat and Meat Products for Export to the United States of America. Royal Decree 993/2014* details the procedures and requirements for official veterinary certification for the export of animal products.

Spanish establishments interested in obtaining approval to export products regulated by FSIS to the United States must submit an application to the External Livestock Commerce. Once MAPAMA completes its review of the application, the SGSE will request a preliminary report of the establishment from the SVO where the establishment is located. After receiving a report from the SVO indicating the new establishment is compliant with United States requirements, the CCA assesses the facility to verify its compliance with FSIS requirements. The FSIS auditors observed that the CCA evaluated the written food safety programs, audited the facilities, and evaluated their compliance with FSIS requirements before granting certification of eligibility to export meat to the United States.

All approved establishments for the export of meat and meat products to the United States are monitored by the CCA on a regular basis with a set frequency based on risk assessment modules for individual establishments on an annual basis. The FSIS auditors reviewed the 2016 and 2017 risk analyses for certified establishments in Catalonia and did not identify any concerns. The CCA conducts supervisory visits once a year at establishments certified to export to the United States. The CCA communicates the FSIS requirements to all levels of inspection personnel via coordination meetings, emails, faxes, etc. Updates and additional instructions to inspection personnel concerning established regulations, programs, and manuals are published and disseminated as information notices. FSIS reviewed information notices regarding changes to

United States requirements and verified this information was appropriately disseminated to in-plant officials.

The procedures for the monitoring are outlined in the document *Regular Monitoring Procedures at U.S. Approved Establishments*. Whenever multiple noncompliances are observed or recurring noncompliances have occurred or a warning of unacceptable status has previously been documented and it has not been answered, the CCA can issue a Notice of Intent to Delist (NOID) or suspend the issuance of export certificates for a product group, a product class, or a process category. If the establishment's measures in response to the NOID are not effective, the CCA can withdraw approval. NOID management follows the guidelines provided in the document *Inspection Procedures for U.S. Approved Establishments*.

The audit of the CCA headquarters, the Cataluña Regional Office, and local inspection offices involved an examination of the periodic supervisory reviews at establishments certified to export to the United States. The FSIS auditors verified the supervisory reviews included monitoring of inspection activities for HACCP, Sanitation SOP and sanitation, pathogen monitoring, environmental sampling procedures, review of supporting documentation that supports the establishment's decision-making process including validation data, and evaluation of any changes that occurred following the previous supervisory visit. The FSIS auditors verified the supervisory reviews by the CCA occurred once a year at establishments certified to export to the United States.

At the local government (establishment) level, Official Veterinarians (OVs), who are government inspectors, have the responsibility to implement and enforce inspection requirements at the establishments certified to export to the United States. Official establishments in the Catalonia autonomous community also hire Asistentes Oficiales de Inspección Veterinaria (AOIVs) that work under the supervision of OVs. The OVs provide government supervision at each establishment while the contract AOIVs assist in performing ante-mortem and post-mortem inspection activities for product intended for export to the United States throughout slaughter operations and at least daily, one per shift during processing. To ensure products comply with United States import requirements, MAPAMA has developed specific instructions for the certification of the products for export to the United States in a document entitled *Procedure for the Export of Pork and Meat Products from Spain to United States*.

The FSIS auditors verified that Spain ensures that source meat products used in processing operations originate only from establishments certified to export to the United States in accordance with Regulation (EC) No. 178/2002 and the *Ministry Order of April 4, 1995, Technical-Sanitary Conditions and Conditions of Authorization Applicable to Establishments of Meat and Meat Products for Export to the United States of America.* Official controls are carried out in the country of origin of the raw material as there is no border control between the Member States of the EU. Spain is not importing raw material from other countries not belonging to the EU.

There are different export procedures and certificates depending on the origin of the raw materials and whether the establishment has an APHIS cooperative agreement. A health attestation is issued by the official services of the CAs and submitted to the Border Veterinarian

Inspection Services, which are responsible for issuing the veterinarian export certificates. The FSIS auditors verified that only pork products originating from animals slaughtered at United States-eligible establishments were processed and exported to the United States under the appropriate export certificate.

Royal Decree 993/2014, Procedure and Requirements of the Official Veterinary Certification for Export, sets forth the procedures and requirements for the official veterinarian export certification and explains the penalties for offenses that violate the provisions of the decree. The veterinary export certificates are printed from CEXGAN, a computer support system for the export of products available on the Ministry of Agriculture, Food and the Environment's website, on security paper provided by the General Directorate of Agricultural Production Health. The veterinary export certificates contain a watermark and two front tapes (one only visible in UV light) plus one tape on the back (only visible in UV light). Once printed, the veterinary export certificates may not be amended. If is necessary to change the information contained therein or include more information, a replacement veterinarian export certificate must be requested or the issuance of a complementary certificate, as applicable.

The national and the regional governments fund the official inspection program. OVs are employees of the government of Spain and subject to administrative policies that apply to all government officials. Based on the *Inspection Procedures for U.S. Approved Establishments* the CAs are responsible for designating and overseeing the activities of the OVs in establishments authorized to export to the United States. The CAs recruit OVs from state veterinary universities and provide them with required general training. The public officials of the CAs (including in-plant inspection personnel) have the same authority as public officials of the national government to take official control actions in establishments certified to export to the United States.

Hiring of official inspection personnel is through personnel selection processes that are regulated by regional rules or legislations. The standard for the qualifications of official veterinarians is given by the selection processes described in *Order Ministerial APA/1322/2008, Selective Process for Entry in the National Veterinary Corps*. The regional authorities are responsible for providing official relief inspectors for the assignments in establishments due to planned or unplanned absences of official inspection personnel. The FSIS auditors verified that in the event of staffing shortages, the CAs contacts an official inspector from a list of eligible official relief inspectors to conduct inspection duties at the establishment. The FSIS auditors verified that all official inspection personnel including available official relief inspectors are direct employees of the government and receive the same training as permanent inspection personnel at establishments certified to export to the United States.

The Catalonia CA utilizes AOIVs as support personnel for the OVs. The AOIVs are employed by a third party, a supplier contracted by the competent health authority of Catalonia by means of public procurement. *Royal Decree 138/2003, Functions and Conditions of Training, Qualification, and Authorization of the Support Personnel for Veterinary Inspection in Slaughterhouses in Catalonia*, establishes the duties to be performed by the AOIV in Catalonia.

The FSIS auditors noted the AOIVs assigned to establishments certified to export to the United States in Catalonia assisted the OVs with performing ante-mortem and post-mortem inspection tasks under the direct supervision of the OVs. Government supervision by the OVs is on premises while the AOIVs are performing inspection duties for product intended for export to the U.S. throughout slaughter operations and at least daily, once per shift, during processing. The *Supervision Procedure of the Official Auxiliaries of Veterinary Inspection* establishes the supervision conducted by the OVs of the tasks performed by the AOIVs. The document list the step-by-step procedures that the OVs conducted during regular supervision of the AOIVs through daily direct observation in a continuous manner and documenting their observations on established forms twice daily and conduct a review of records at the end of the day of slaughter. FSIS auditors reviewed these records and found that they followed the procedures established in the above stated document and included initials of the OV who carried out the supervision, the result, any corrective actions that were applied, time and the departure control was taken. Any deviation detected by the OV is considered corrected when the OV verifies that the AOIV performs the task in an adequate manner. The FSIS auditors reviewed the 2015 Department of Health Contract Announcement for AOIV inspectors in Catalonia and reviewed payroll documentation showing the awarded contractor paid the AOIVs.

The type of operations that require inspection coverage is outlined in the document *Inspection Procedures at Approved U.S. Establishments*. The FSIS auditors reviewed the records documenting the inspection tasks to confirm that OVs were at each audited establishment when inspection was required, at least once per shift during processing operations, and that OVs or AOIVs were on the post-mortem slaughter line during all slaughter operations.

The CCA ensures that inspection personnel have appropriate education credentials, and necessary training and experience to carry out inspection tasks. The standard for the qualifications of official veterinarians is given by the selection processes described in *Order Ministerial APA/1322/2008*. Eligible applicants must be in possession of, or in a position to obtain, a degree in veterinary medicine. The selection process requires applicants to undergo a system of examinations covering topics related to administration and public policy, agri-food sectors and markets, livestock and fisheries, animal health, public health and environmental health. The CCA and the CAs organize annual training courses for the SOVs. The CCA offers a course annually on general FSIS regulations to inspectors and supervisors assigned to establishments certified to export to the United States.

The FSIS auditors verified that the CCA has implemented and conducted ongoing training programs intended to ensure that in-plant inspection personnel are aware of specific food safety and inspection requirements that pertain to Spain's meat export to the United States. The CCA has routinely conducted multiple training sessions since the FSIS audit in 2015. FSIS verified certificates of participation from the following training courses for official inspectors and supervisors. These courses covered: individual performance evaluation methods for supervisors; supervision of authorized establishments to export meat and meat products to the United States; regulatory requirements for export of meat and meat products to the United States; official controls in slaughterhouses authorized to export to the United States; and official control of production lines in ready-to-eat (RTE) establishments authorized to export to the United States.

The FSIS auditors verified certificates of participation from the following training courses for AOIVs: animal welfare and official auxiliary of veterinary inspection. The CCA makes the training materials available for review on their Web site. The FSIS auditors observed the in-plant inspection personnel while they were conducting their inspection activities and concluded that they have sufficient training to perform their duties.

The 2015 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 including the findings for ventilation. The FSIS auditors verified the completion of corrective actions in response to the FSIS audit findings in 2015. The CCA re-evaluated their procedure for periodic supervision of official inspectors and developed a new document entitled *Regular Monitoring Procedures at U.S. Approved Establishments*. The CCA developed a training course on individual performance evaluation methods for supervisors to explain the new methodology. The training course took place in April 2016. The CAs conduct assessments of the inspectors' personalized performance between once a year and once every two years based on the number of inspectors assigned to the establishments certified to export to the United States. The SGSE will schedule accompaniment visits to verify onsite performance assessments carried out by the CAs. These accompanying visits are scheduled to ensure that all CAs are visited onsite at least every two years. The FSIS auditors reviewed multiple records of performance assessments and one report from an SGSE accompaniment visit.

All laboratories operate in accordance with criteria aligned with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standard. Spain's laboratories are part of the administrative and technical support of the CCA's inspection system and maintain accreditation through the Spanish Accreditation Body (ENAC). Five official microbiological laboratories in Spain perform microbiological tests for establishments certified to export to the United States. The FSIS auditors 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.

The CCA and CAs jointly developed the National Residue Investigation Plan according to Council Directive 96/23/EU to ensure that MSSSI meets United States requirements. This program complies with *Royal Decree 1749/1998, Control Measures and Investigation Plan for the Substances or Metabolites that May be Administered to Animals*, in order to detect them during any stage of the obtaining or processing phases of animal source products. The 2016-2020 PNCOCA contains specific programs for the official control of contaminants in food, control of the presence of pesticides, and collection of the data corresponding to veterinary medicinal residues products and banned substances. The CCA conducts random sampling and testing of internal organs and fats for targeted residues.

FSIS determined that Spain's government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at establishments certified to export to the United States.

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

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

The FSIS auditors performed onsite observations, interviewed MSSSI personnel, and reviewed records maintained at CCA, at the Cataluña Regional Office, and at local inspection offices in each audited establishment. The FSIS auditors verified whether the CCA provides appropriate oversight and direction to inspection personnel to use their regulatory authority to enforce requirements for Spain's meat food safety system. The FSIS auditors, accompanied by the CCA representatives, observed the performance of verification activities by the in-plant inspection personnel.

The verification activities observed by the FSIS auditors included ante-mortem inspection; humane handling and slaughter verification; post-mortem inspection; zero tolerance verification of establishments' procedures for controlling feces and ingesta contamination; *Salmonella* performance standard sample collection; analysis of establishment generic *E. coli* sample results; analysis of government and establishment *Listeria monocytogenes (Lm)* and *Salmonella* verification results of finished product; *Lm* verification results of food contact surfaces (FCS)and non-contact environmental samples and verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities. Additionally, the FSIS auditors reviewed the performance evaluations of in-plant inspection personnel and the completion of supervisory reviews of establishments certified to export to the United States. The FSIS auditors did not identify any concerns related to these document reviews.

The FSIS auditors verified that in-plant inspection personnel's ante-mortem inspection activities complied with EU regulations and the *Royal Decree 37/2014, The Regulations Regarding the Protection of Animals at the Time of Killing.* The FSIS auditors also verified that in-plant inspection personnel in the audited slaughter establishments in Catalonia complied with the *Animal Welfare Control Plan in Slaughterhouses in Catalonia for 2016-2020* and the *Ante-mortem Inspection in the Slaughterhouses in Catalonia for Domestic Ungulates, Poultry, and Rabbits*. Only swine that originates from Spain or countries deemed by APHIS as free of FMD from countries and establishments eligible to the United States, rinderpest, African swine disease, CSF or SVD are slaughtered in establishments certified to export to the United States. The slaughterhouse receives documentation from the farm of origin of the animals. The inspection personnel reviewed the incoming registration and identification documents with each load/truck and observed all animals from both sides while at rest and in motion in unloading and

ante-mortem inspection pens before slaughter in order to determine whether the animals are fit for slaughter.

The FSIS auditors observed and verified that all animals had access to water at all times in holding pens, including the suspect pen, and that if an animal were to be held overnight, feed would be provided. For each inspected lot, the MSSSI inspection personnel document the results of ante-mortem inspection and numbers of livestock on pen cards accompanying each lot to slaughter. The inspection personnel document results of humane handling and slaughter verification on records kept in logs developed by the CAs.

Each audited establishment maintained a designated holding pen for further examination of sick or suspect animals. The OV examines any suspect livestock, identified with conditions that may preclude slaughter, and documents results on a form, designated for ante-mortem inspection. Additionally, the OV documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form and all products are rendered unsuitable for human food with denaturant prior being rendered. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock.

The FSIS auditors verified through direct observation, onsite record reviews, and interviews whether the inspection system ensures United States requirements are met for livestock facilities and humane handling and slaughter. In-plant inspection personnel verify that operators comply with humane handling and slaughter requirements. The FSIS auditors observed the stunning process at audited establishments and verified that each establishment utilized a carbon dioxide gas chamber and verified adequate stunning prior to shackling and hoisting. The inspection personnel also verify gas concentration and its exposure time to render swine insensitive to pain. The inspection personnel also observe the loss of consciousness and accompanying indicative signs of adequate stunning before swine are shackled and bled.

The CCA is responsible for assigning OVs to establishments authorized to export to the United States and the CCA have defined the types of operations that require inspection coverage in the document entitled *Inspection Procedures for Approved Establishments*. The CCA maintains daily inspection in the establishments certified to export to the United States when product is being produced for the United States in accordance with their established criteria. The OVs are responsible for supervising on-line AOIVs and post-mortem inspection activities, including disposition of suspect carcasses and parts. Regulation (EC) No. 854/2004, Annex I provides that line speeds and the number of inspection personnel assigned allow for proper inspection. The FSIS auditors verified that the OVs at each slaughter establishment were aware of the required staffing and that the number of OVs and supporting AOIVs conducting post-mortem inspection activities were sufficient for the existing production volume and line speed in all audited establishments. OVs were responsible for performing off-line verification activities such as ante-mortem inspection of animals in motion and at rest, collection of samples for laboratory analyses, and verification procedures in the deboning rooms.

The FSIS auditors verified that written procedures are in place instructing inspection personnel how post-mortem inspection is to be performed, including visual inspection, palpation, and incision of relevant portions of the animal as described in Regulation (EC) No. 854/2004 and

Postmortem Inspection in Catalonia Slaughterhouses for Domestic Ungulates, Poultry, and Rabbits. The FSIS auditors verified through direct observation the post-mortem inspection by OVs, with the support of AOIVs, to verify implementation of proper presentation, identification, examination, and disposition of carcasses and parts. The FSIS auditors observed OVs with support of AOIVs performing examination of swine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes. The FSIS auditors verified post-mortem examinations were performed in accordance with EU regulations.

The FSIS auditors observed the off-line OVs in the two audited slaughter establishments and OVs assigned in the four audited processing establishments conducting inspection at least once per shift during process operations and on-line inspection during all slaughter operations for product exported to the United States. Disposition of suspect animals during ante-mortem and post-mortem inspection, and verification of acceptability of the final product, are the responsibility of the OVs, who prepare daily post-mortem disposition reports to document their official control actions. The MSSSI verification procedures and instructions are provided in the *Inspection Procedures for Approved Establishments.* This document details specific instructions for verification of United States requirements.

The OVs' verification activities include direct observation and review of records related to Sanitation SOPs, sanitation, HACCP, residue sampling, and *Salmonella* spp. and generic *E. coli* sampling in accordance with the *Inspection Procedures for Approved Establishments*. The CCA develops specific risk-based verification frequencies that are detailed in the establishment-specific document entitled *Programming of Official Inspection Procedures*. The OVs are responsible for drafting monitoring plans based on those frequencies, which include yearly and weekly schedules. The CAs verifies that inspection personnel perform verification procedures at the frequency identified in the monitoring plan with results documented electronically. The FSIS auditors verified the OVs were conducting verification activities at the audited establishments at the frequency identified in their monitoring plans.

At each audited slaughter establishment, the FSIS auditors observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during dressing procedures and viscera removal. The FSIS auditors also observed in-plant inspection personnel conducting daily verification of the adequacy of critical control point (CCP) for zero tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors did not observe any systemic sanitary dressing concerns or zero tolerance deviations during the audit.

The supervisory officials of CAs conduct reviews of establishments certified to export to the United States within their autonomous community at the frequency determined by the CCA based on their risk analysis to meet 9 CFR Part 327.2 requirements. The FSIS audit of the CCA, Cataluña Regional Office, and local inspection offices involved an examination of the periodic supervisory reviews at establishments certified to export to the United States. The procedures for supervisory reviews are detailed in the document *Regular Monitoring Procedures at U.S. Approved Establishments*. Supervisory visits are recorded on the *Inspection Form for Official Examination of U.S. Authorized Establishments*. The FSIS auditors verified the supervisory reviews included monitoring activities for HACCP, Sanitation SOP and sanitation, pathogen

monitoring, environmental sampling procedures, review of supporting documentation that supports the establishment's decision-making process including validation data, and evaluation of any changes that occurred following the previous supervisory visit. The FSIS auditors verified the supervisory reviews occurred at the frequency determined by the CCA based on the risk analysis.

There are two types of supervisory reviews. The first type evaluates the adequacy of the establishment's food safety system and determines whether it continues to meet regulatory requirements for exporting to the United States. The second type evaluates the capability and performance of inspection personnel to conduct inspection activities at establishments certified to export to the United States.

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.

The FSIS auditors 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 CAs. The review of documented assessments associated with supervisory reviews indicated that these reports were documented, identifying both positive and negative results with the latter having documented actions resolved expediently and verification of those actions by the OV. The CA's supervisory officials verified that the corrective actions for all identified deficiencies had been implemented and verified by the inspection personnel during their next scheduled supervisory visit.

The CCA has adopted consistent with the requirements FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, and its procedures concerning issuing noncompliance reports. The FSIS auditors verified that the OVs have identified and documented noncompliances on registries of deficiency (RD) reports. The OVs closed the RDs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventative measures. At the six audited establishments, the FSIS auditors reviewed a sample of open and closed RDs issued for Sanitation SOP, HACCP, and SPS noncompliances. The FSIS auditors did not identify any negative trends based on the supervisory review records and inspection-related verification activity records reviewed. However, during two establishment visits, the FSIS auditors identified:

- The OVs did not adequately verify that establishments maintained sanitation programs relating to ventilation (condensation) and the protection of product. These deficiencies were primarily associated with SPS and Sanitation SOP requirements. This is a repeat finding from the 2015 FSIS audit, which indicates that MSSSI did not adequately verify that the corrective actions were effective at preventing reoccurrence of the identified deficiency.

The FSIS auditors verified that there is a separation of product eligible for export to the United States from product not meeting requirements. OVs verify that operators comply with the requirements for separation of product destined for the United States. The EU regulations and the *Inspection Procedures for Approved Establishments* contain requirements that establishments certified to export to the United States ensure complete separation of product eligible for export to the United States. OVs verify requirements for separation of products and document results within QUAESTOR as well as via periodic supervisory review reports prepared by the CCA and the CAs. The FSIS auditors verified use of product codes with designated codes for export to the United States and segregation of final boxed product. The FSIS auditors verified that establishments had written programs to define separation of products destined for export to the United States.

The CCA maintains adequate verification procedures to ensure sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions.

The FSIS auditors reviewed the legislation, regulations, official instructions, decrees, and guidelines of the CCA and verified that MSSSI uses its legal authority to require that establishments certified to export to the United States develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditors' verified that the CCA enforces EU sanitary regulations. The CCA has adopted FSIS requirements consistent with 9 CFR Parts 416.1 to 416.5 to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions.

The OVs conduct verification of sanitary conditions in consistent with FSIS Directive 5000.1 and in accordance with the *Inspection Procedures for Approved Establishments*, which includes 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 frequency of sanitation inspection verification tasks is risk-based and operational Sanitation SOP verification is scheduled daily for inspection personnel. The OVs entered sanitation verification data into QUAESTOR, which can be analyzed by the CCA and CAs to detect trends of noncompliance. The FSIS auditors verified that inspectors carry out

the verification frequency of sanitation requirements as they vary (yearly, monthly, weekly, daily) and are scheduled in the establishment-specific annual Program of Inspection Procedures. The CCA demonstrated that it enforces these requirements at establishments certified to export to the United States.

The FSIS auditors reviewed the design and implementation of sanitation programs at the audited establishments. The FSIS auditors observed the OVs conducting pre-operational sanitation verification of slaughter and processing areas in two of the audited establishments. The OVs' 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. The OVs conducted this activity in accordance with the established procedures including a pre-operational record review of the establishment monitoring results and an organoleptic inspection of FCS of facilities, equipment, and utensils; as well as an assessment of SPS requirements (e.g., ventilation, condensation, and structural integrity).

The FSIS auditors observed the OVs' verification of operational sanitation procedures in all six audited establishments, comparing the overall sanitary conditions of all audited establishments to the MSSSI inspection verification result documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all establishments. The FSIS auditors also examined the MSSSI documentation of inspection verification results documented in QUAESTOR, the RDs, and supervisory reviews of establishments. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employees specified as being responsible for the implementation and monitoring of the Sanitation SOPs authenticated these records with initials or signatures and the date observations were made.

The FSIS auditors identified sanitation findings in three establishments related to implementation of SPS and Sanitation SOPs while conducting a walk-through at the audited establishments to assess the CCA's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations. These were determined to be isolated findings and are detailed in the FSIS Establishment Checklists included in Appendix-A of this report. In response to the FSIS auditors' observations, the in-plant inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination.

The FSIS auditors identified the same finding observed during the 2015 FSIS audit related to ventilation (condensation), indicating that the controls in place are not effective. Both establishments where beaded condensation was observed have written programs for monitoring condensation. A recent supervisory review of one of the two establishments where condensation was observed identified beaded and dripping condensation with product affected. This finding was documented by the CAs in an RD. A review of recent RDs did not show any additional incidents of condensation documented. The continued observance of deficiencies relating to ventilation (condensation) indicates the 2015 corrective actions and measures to prevent recurrence taken by the establishment were ineffective. This finding is discussed under

Component Two: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations.

The FSIS auditors' analysis and onsite verification activities indicate that the meat inspection system of Spain requires that all establishments certified to export to the United States develop, implement, and maintain sanitation programs, including Sanitation SOPs, to prevent the creation of insanitary conditions and direct product contamination.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The CCA adopted FSIS requirements consistent with 9 CFR Part 417 for the implementation of HACCP. The CCA, through the *Questionnaire for the Authorization for Fresh Meat and/or Meat Products for the United States of America,* outlines required legislation for HACCP requiring establishments exporting to the United States to develop, implement, and maintain HACCP programs.

At the two audited slaughter and processing and four processing only establishments, the FSIS auditors conducted an onsite review of the establishments' HACCP systems, including hazard analyses, HACCP plans, and CCP records as well as inspection verification records and direct observation of in-plant inspection verification activities. The actions to be taken by inspectors of establishments certified to export to the United States are identified in the document entitled *Inspection Procedures for U.S. Approved Establishments*. Whereas actions taken by supervisors of establishments certified to export to the United States are identified in the document entitled *Regular Monitoring Procedures at U.S. Approved Establishments*. The in-plant inspection personnel at establishments certified to export to the United States conducted daily verification of HACCP plans co9nsistent with FSIS Directive 5000.1 and HACCP requirements. The inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping. The CCA and CAs conduct HACCP program reviews during supervisory reviews. The design and implementation of all establishments' HACCP programs are reviewed yearly. Additionally, the CCA and CAs supervisory reviews of inspection personnel's HACCP verification activities were providing adequate oversight.

The FSIS auditors observed the in-plant inspection personnel conducting HACCP hands-on verification activities associated with zero tolerance CCP verification for visible milk, ingesta and feces on swine carcasses and made a direct examination of swine carcasses at both audited slaughter and processing establishments. The FSIS auditors and inspection personnel did not observe any deviations from the critical limits.

In addition, the FSIS auditors reviewed in-plant inspection HACCP verification results associated with the zero tolerance CCP documented by the OVs and the establishment generated

monitoring and verification records. The review of these records and establishments' corrective actions in response to deviations from zero tolerance critical limits that were documented indicated that the establishments' corrective actions were adequately documented and verified by OVs as meeting all HACCP corrective action requirements.

The FSIS auditors reviewed both in-plant inspection verification as well as establishment-generated monitoring and verification records for CCPs at all four audited establishments manufacturing RTE not heat-treated-shelf stable products. These products 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 water activity and pH in their processes.

The FSIS auditors review of the HACCP plans for heat-treated – shelf stable products included the verification that establishment have implemented CCPs to achieve the intended food safety objectives towards eliminating *Lm* and *Salmonella* spp. in finished products. These HACCP plans included supporting documentation for CCP control measures verified by the CCA that consisted of several types of documents, such as peer-reviewed scientific articles and challenge and inoculated pack studies. In-plant verification data presented by the establishment consisted of microbiological test results, measurements of water activity (Aw) and pH of products, and in-plant observations.

The FSIS auditors confirmed that in order 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 ongoing testing for *Lm* in the finished product, on FCS, and in the processing environment as mandated by the CCA. The FSIS auditors 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.

The FSIS auditors' analysis and onsite verification activities indicate that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

FSIS based its verification of Spain's chemical residue testing program on information contained in Spain's 2017 National Residue Monitoring Plan (NRMP) and the 2016 NRMP results. Specific animal tissues are contained in the *Spain Results Pig 2016* document. The CCA's NRMP is based on Council Directive 96/23/EC and Regulation (EC) No. 882/2004. Spain is responsible for the control and diagnosis of residues and chemical contaminating elements

present in meat and processed meat. The CCA has the legal authority for surveillance and to prevent the entry, commercialization, and outlet of products of animal origin and with chemical residues that exceed the maximum levels of residues accepted nationally and internationally.

The PNCOCA for 2016-2020 contains a specific framework program for the official control of contaminants in food, one for the control of the presence of pesticides, and another for the collection of the data corresponding to veterinary medicinal residue products and banned substances. The CAs implement these official controls and submit the data, corresponding to the controls made, noncompliances, and measures adopted to MSSSI. Measures for the control of residues and veterinary drugs are discussed in the National Commission for Residue Monitoring Plan and are implemented in accordance with *Royal Decree 1749/98* that provides the legal basis for the annual residue plan. These documents prescribe conditions of chemicals used in the production of meat, including animal feed; provide authority to prohibit the use of compounds that may present public health risks; and provide the ability to control and monitor industrial and environmental chemicals. These documents also indicate that MSSSI maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The annual national residue monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The plan specifies the detection method, the method of analysis to be used, the matrix to be collected, the tolerance, and the total number of samples to be collected; in this case, FSIS' concern is swine since it is the only species of export to the United States.

The FSIS auditors verified implementation of the NRMP at the two audited slaughter and processing establishments. The OV conducts random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues. The official monitoring examinations are conducted according to the NRP, which is defined every year. The plan lists the residue group, the number of samples for the group, and the matrix for each month. The individual OVs randomly select the carcass to sample. The OVs complete the laboratory submission form, and a copy is packaged in the sample shipment cooler, which the OV secures with a numbered seal to maintain integrity.

The FSIS auditors verified that the CCA's implemented sampling protocol mandates test and hold practices (holding or controlling product until results become available) to ensure that MSSSI verifies acceptable residue results prior to issuing certification for export to the United States. In the event any sampled lot has a positive or violative result of a chemical compound, the OV also issues a non-conformance/noncompliance report to the establishment. FSIS' review of documentation at the two audited slaughter and processing establishment local inspection offices verified that in-plant government inspection personnel were collecting samples of the required matrices for detection and adhered to the prescribed sample collection schedule. FSIS' review of the monitoring results for 2016 at these establishments indicates that no violative samples were detected.

The FSIS auditors verified that the CCA's official control measures and enforcement actions of the implementation of the NRMP are in accordance with Council Directive 96/23/EC. If a positive or violative result occurs, the NRL notifies the CCA, CA, and OV via email. The following procedures are followed by the CCA when notified of positive or violative results: identify the animal and farm of origin; investigate the cause of the violation at the farm; safeguard the public health by product disposition; intensify the checks on the animals and products from the farm; and impose criminal or administrative penalties against any person who is responsible. Spain, as a member of the EU, has residue plans that are acceptable by EU standards and, recognized as equivalent to FSIS' criteria.

The FSIS auditors verified that MSSSI has implemented the NRMP in accordance with Council Directive 96/23/EC. The CCA has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet FSIS criteria. The program contains provisions that ensure any product with residues exceeding established tolerances is condemned and ineligible for use as human food. In addition, to prevent the violations from recurring, the CCA investigates the cause of the residue violation and initiates intensified sampling from the same supplier.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included a review and analysis of Regulation (EC) No. 2073/2005, which contains specific rules for testing and minimum sampling, and MSSSI Circular 1/2013, *Control of the Hygiene of the Slaughter Process Programs of Reduction of Pathogens in Authorized Slaughterhouses that Export Meat to the U.S.* that contains the regulatory requirements for establishments exporting meat and meat products to the United States.

The CCA requires all slaughter establishments to implement an establishment conducted microbiological testing program to assess the effectiveness of sanitation and process control. Establishments either implement sampling and testing for generic *E. coli* in raw carcasses as established in 9 CFR Part 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. Spain has adopted requirements consistent with 9 CFR Part 310.25(a) for generic *E. coli*, with the exception of the following equivalent measures: Spanish establishments use a gauze swab sampling tool and accredited private microbiology laboratories use an Association of Analytical Communities (AOAC) approved method or AOAC Petrifilm method to analyze samples for generic *E. coli*.

The CCA conducts verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample

integrity. The CCA uses the test results to verify establishment slaughter dressing controls for fecal contamination are adequate. Furthermore, the in-plant inspectors verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded. The CCA requires that test results for product that is presented for export to the United States be found compliant prior to the export health certificate being approved. Additionally, the CCA mandates that all establishments have a recall program in place and a trace back system for product produced.

The FSIS auditors verified through document reviews, direct observation, and interviews of MSSSI inspection personnel that the two audited slaughter establishments had implemented a microbial process control testing program to verify process control; *E. coli* testing of livestock carcasses with requirements consistent with 9 CFR Part 310.25(a). The FSIS auditors reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. The FSIS auditors' review of the establishments' microbial process control testing programs and the establishments' records did not reveal any noncompliance or concerns.

The CCA applies a sampling and testing program to verify that the establishments certified to export to the United States meet the requirements consistent with 9 CFR Part 310.25(b) and the FSIS *Salmonella* performance standard for hogs. The specific requirements are provided in the *Official Microbiological Verification Program for Slaughterhouses.* The FSIS auditors reviewed the implementation of the program within certified slaughter establishments along with results and records documenting performance standards. FSIS has determined that the use of alternative analytical methods, PEE/LSPV/012, PEE/LSPV/226, and PEE/LSPV/096 for the purpose of *Salmonella* testing in raw and RTE products meets the established criteria.

The FSIS auditors verified that all establishments certified to export to the United States MSSSI sample collection procedures are in accordance with the sample collection protocols. The planning of the in-plant inspection verification is made in accordance with the *Official Microbiological Verification Program for Slaughterhouses.* MSSSI performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/pathogen reduction studies) to determine the ongoing effectiveness of the inspection system for *Salmonella* performance standards.

The FSIS auditors reviewed records, including *Salmonella* spp. results, for the last year at the two audited slaughter and processing establishments. Results showed no *Salmonella* set failures during the period reviewed. In addition, the FSIS auditors observed and verified the OVs' collection procedures are in accordance with the sample collection protocols described in the aforementioned regulatory requirements. FSIS verification activities confirm aseptic techniques, and procedures for sample collection from porcine carcasses for *Salmonella* testing. The demonstrated methodology is consistent with FSIS' method.

The FSIS auditors performed verifications through document reviews and direct observation at the four audited establishments producing RTE products. The FSIS auditors verified that the CCA had adopted and implemented procedures and requirements consistent with FSIS

regulatory requirements related to the control of *Lm* in the post-lethality exposed RTE environment of the processing facilities as outlined in 9 CFR Part 430.

The CCA regulatory microbiological verification program *Official Microbiological Verification Program in Food Production Lines Ready for Consumption (RTE)* includes additional post-lethality exposed RTE product sampling at meat processing establishments that are certified to export to the United States. This program differs from the national microbiological verification program administered by the CAs 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 requirements that are adopted by Spain, RTE product is considered adulterated if it contains *Lm* or *Salmonella*, or if it comes into direct contact with a FCS that is contaminated with *Lm*. The FSIS auditors reviewed testing results for establishments producing RTE product for the last year showing that MSSSI verification testing and establishment verification testing produced no positive test results in products tested for *Lm* or *Salmonella* or in product contact surfaces or non-product contact surfaces for *Lm.*

The FSIS auditors performed an onsite audit of the Public Health Laboratory a government microbiological laboratory in Valencia. The laboratory performs MSSSI verification analyses for RTE product that includes *Lm* and *Salmonella* and *Lm* analysis of exposed finished product and *Lm* analysis of contact and non-contact surfaces (environmental). The FSIS auditors verified that ENAC has accredited the laboratory as equivalent to the ISO/IEC 17025:2005 standard. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support MSSSI's inspection program for certified establishments eligible to export to the United States. The laboratory uses the following analytical confirmatory methods for *Listeria* PEE/LSPV/068 (ALOA ONE DAY) and *Salmonella* PEE/LSPV/012 (ISO/IEC 6579).

The CCA and ENAC audits the laboratory annually. The laboratory also performs internal audits according to their Quality Assurance Manual. The laboratory has procedures for proficiency testing. The CCA verifies that United States equivalent methods are used for samples from establishments certified to export to the United States. The FSIS auditors reviewed the most recent CCA and ENAC annual audit reports of the laboratory. These audits have reported a few non-conformances, which were addressed and corrected by the laboratory's quality control department.

The FSIS auditors observed and verified sample receipt and handling. The FSIS auditors verified that the government laboratory performs a timely analysis of samples, and that they report the amount of analyzed samples and the results to MSSSI in a timely manner, apply

approved analytical methodologies, and have quality assurance programs. No concerns arose because of these observations and reviews. The FSIS auditors verified that ENAC conducts the prescribed annual audit of the laboratory quality system to ensure United States requirements are met.

The FSIS auditors verified that Spain's meat inspection system is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The microbiological testing program as described is consistent with the criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on October 19, 2017, in Madrid, Spain with MSSSI. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

An analysis of each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The Central Competent Authority (CCA) did not adequately verify that establishments met government sanitation requirements that ensure ventilation is sufficient to control condensation in order to protect product and prevent the creation of insanitary conditions. The same finding was noted during the 2015 FSIS audit. The CCA's verification efforts did not ensure that the establishments' corrective actions were effective at controlling condensation to prevent recurrence of noncompliance.

During the audit exit meeting, the CCA committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Food Group S.A. Carretera Toledo-Avila Km 27,4 Torrijos (Toledo)	10/06/2017	14	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	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	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

During the walkthrough of the establishment, FSIS auditors observed the following deficiencies:

41/51 Ventilation:

- RTE slicing and packaging room: beaded condensation had developed on multiple overhead refrigeration cooler ducts located between two processing lines.
- Raw ham salting cooler: bins of salted ham product was not covered to prevent the possible contamination of condensation as per the establishment's SPS program for this cooler.

The auditors did not observe any product contamination as no dripping of condensation was observed at the time of the observation.

46/51 Sanitary Operations:

Raw ham salting cooler: S/S bins of salted ham product were stacked three high. Salted pork product in the bins were exposed to the underside of the S/S bin above it as there was no covering to protect the product from possible cross contamination from the above bin and also the forklift forks that move the bins onto and off one another when stacked.

The auditors did not observe any product contamination at the time of the observation.

Each of these identified incidents creates a potential cross contamination condition of exposed RTE and raw pork product. These observations indicate ineffective maintenance and monitoring of overhead structures and verification of establishment's SPS programs and verification of sanitary operations in the handling of exposed pork product by CCA inspection personnel which are crucial to an establishment’s ability to produce a clean, safe, and wholesome product.

A review of establishment and inspection verification documents provided no evidence that these deficiencies were previously identified within the records reviewed.

Corrective actions were taken by the establishment and verified by MSSSI with additional measures to prevent the reoccurrence to be provided to inspection personnel.

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 Alimentacion, S.A. Carretera Logrono S/N Albelda de Iregua (La Rioja)	10/11/2017	16	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/11/2017

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
Redondo Iglesias S.A. Carretera Madrid Valencia Km 132 Utiel (Valencia)	10/13/2017	20	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
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	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/13/2017

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
Industrias Carnicas El Rasillo S.A. San Mames S/N El Rasillo (La Rioja)	10/10/2017	24	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/10/2017

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
Pernils Llemena S.A Ct Girona a Les Planes Km 23 Sant Aniol de Finestres (Girona)	10/03/2017	30	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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

Audit of Est. 30 - Pernils LLemena, S.A. located in Sant Aniol de Finestres was not audited as planned due to safety concerns for FSIS auditors during a general citizen's strike resulting from political tensions from the Catalonia independence referendum. The establishment canceled production.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/03/2017

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
Frigorificos Costa Brava SA Ct de Riudellots a Cassa S/N Riudellots de la Selva (Girona)	10/04/2017	33	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

16/51 HACCP: Recordkeeping - Corrective Actions:

The FSIS auditors review of HACCP records for the establishment's corrective actions for deviations relating to findings of fecal or ingesta contamination during their CCP verification tasks consistently identified the monitoring employee as the root cause of the deviation. The establishment's proffered and accepted corrective actions in response to the government official's findings of fecal or ingesta contamination during the performance of their inspection tasks, consistently identified the establishment's monitoring employee as the root cause of the deviation.

41/51 Ventilation:

During the walkthrough of the establishment the FSIS auditors' observed beaded condensation in multiple areas of the packaging room and in one area over exposed product; however there did not appear to be any dripping of condensation at the time of the observation. This product was not eligible for export to the United States.

It should be noted that during FSIS' pre-operational verification walkthrough of the slaughter area, MSSSI did identify areas overhead where condensation and moisture were not identified by the establishment.

In both instances the government officials took regulatory control to ensure exposed product and product contact surfaces were retained or rejected and that the establishment restored sanitary conditions. MSSSI will verify the establishment's additional measures to prevent the reoccurrence.

During the 2015 FSIS audit a similar deficiencies was identified relating to condensation. The establishment's previous corrective actions included multiple actions to address air flow and the development of a SPS program designed to monitor areas daily and take action when condensation is observed. These preventative measures do not appear to be effective at preventing reoccurrence.

FSIS auditors did identify that the establishment and MSSSI have identified deficiencies with ventilation - condensation. MSSSI's verification of actions taken by the establishment to prevent the reoccurrence of these types of deficiencies does not appear to be effective or have not been properly implemented by MSSSI.

46/51 Sanitary Operations - Swine Carcasses:

During the walkthrough of the establishment FSIS auditors observed a 1-1 ½ in diameter black gel like substances (appeared to be rail lubricant) located on the medial/ posterior portion of the leg/ham area on 2 carcasses in the carcass cooler that were held for further processing.

The establishment failed to prevent the incidental contamination of carcasses with rail dust. These observations indicate ineffective maintenance and monitoring of overhead structures and verification of establishments SPS programs by CCA inspection personnel which are crucial to an establishment's ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

In both cases, the government officials took regulatory control to ensure the carcasses were reprocessed to restore sanitary conditions and will verify establishment's additional measures to prevent the reoccurrence.

MSSSI will provide FSIS measures taken to address the identified deficiency in conducting sanitary operations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/04/2017

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
Patel, S.A.U. Carretera Vic-Olot Km 11 08511 Santa Maria Corco (Barcelona)	10/02/2017	37	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

46/51 Sanitary Operations - Swine Carcasses

During the walkthrough of the establishment FSIS auditors observed black smears (appeared to be rail dust) on multiple carcasses located on the transfer rail leading into the carcass cooler as well as inside the cooler for pork carcasses that were held to be further processed.

The establishment failed to prevent the incidental contamination of carcasses with rail dust. These observations indicate ineffective maintenance and monitoring of overhead structures and verification of establishments SPS programs by CCA inspection personnel which are crucial to an establishment's ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

The government officials took regulatory control to ensure the carcasses were reprocessed to restore sanitary conditions and will verify establishment's additional measures to prevent the reoccurrence.

MSSSI will provide FSIS measures taken to address the identified deficiency in conducting sanitary operations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/02/2017

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

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

SECRETARIA GENERAL DE SANIDAD Y CONSUMO

DIRECCION GENERAL DE SALUD PUBLICA, CALIDAD E INNOVACION

SUBDIRECCION GENERAL DE SANIDAC EXTERIOR

JT/482018

Ms. Mary H. Stanley

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

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

March, 23 2018

In relation to the final audit report for the "on site audit" conducted by FSIS of Spain's meat inspection system from September 27 through October 19, 2017,please find enclosed information about the corrective actions taken by Spain to address the audit findings (Annex 1). Additionally, we are enclosing specific comments regarding the information provided in the audit report (Annex 2)

Sincerely,
Fernando Carreras Vaquer
Deputy Director General for Foreign Health

P° PRADO, 18, 7°
28071 MADRID
TEL: 915962062
FAX: 915964409

ANNEX 1

CORRECTIVE ACTIONS

The FSIS auditors identified the following finding:
Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- *The Central Competent Authority (CCA) did not adequately verify that establishments met government sanitation requirements that ensure ventilation is sufficient to control condensation in order to protect product and prevent the creation of insanitary conditions. The same finding was noted during the 2015 FSIS audit. The CCA´s verification efforts did not ensure that the establishments´ corrective actions were effective at controlling condensation to prevent recurrence of noncompliance.*

Corrective actions taken by Spain::

On November 27, 2017 a meeting was held in the Ministry of Health, Social Services and Equality (MSSSI) (CCA) with the representatives of the regional competent authorities (CA) and to the 24 authorized establishments to export meat and meat products to USA. During the meeting, findings of the FSIS audit were explained. It was also indicated the need to review the ventilation conditions in the establishments to prevent condensation from causing unhygienic conditions.

After this meeting, in December 2017 an instruction to reinforce the ventilation controls was sent to the regional authorities in order to review the ventilation conditions in the 24 authorized establishments. This action has already been implemented and we have specific information on how each company is strengthening its controls to detect and eliminate condensation. With this measure and with the controls scheduled for 2018, a follow-up will be executed to check how ventilation conditions improve in all authorized establishments.

INDIVIAL AUDITS TO ESTABLISHMENTS:

ESTABLISHMENT Nº 14 – CAMPOFRIO FOOD GROUP S.A.

Based on the content of the report *"Corrective Actions were taken by the establishment and verified by MSSSI with additional measures to prevent the recurrence to be provided to inspection personnel"* we understand that we are not required to provide any additional information.

ESTABLISHMENT Nº 33 – FRIGORIFICOS COSTA BRAVA

16/51 HACCP: Recordkeeping - Corrective Actions:
The FSIS auditors review of HACCP records for the establishment's corrective actions for deviations relating to findings of fecal or ingesta contamination during their CCP verification tasks consistently identified the monitoring employee as the root cause of the deviation. The establishment's proffered and accepted corrective actions in response to the government official's findings of fecal or ingesta contamination during the performance of their inspection tasks, consistently identified the establishment's monitoring employee as the root cause of the deviation.

Corrective actions:

The inspectors documented a Record of Deficiencies in the application QUAESTOR Nº 20171997EVB. We obtain the immediate actions from the application and the long-term planned

actions were verified with correct result by the Official Veterinary Services assigned to the establishment.

ESTABLISHMENT REPLY Immediate Action(s)):
Verbal instructions are given to the person in charge of the abattoir and to the quality controllers responsible for conducting the PCC1´s effectiveness checks, in order that they include research and corrective measures concerning the source of contamination, as well as the cause of non-detection by PCC1, in the event of an irregularity being detected. Both causes shall be recorded in the same section (Identification of causes) of the corrective measures record for PCC1 check(RQ-PC-40). Similarly, corrective actions regarding causes and preventive measures shall be taken.

ESTABLISHMENT REPLY (Additional Action(s)):
Modification of the PCC1 Effectiveness Check Instructions document (IQ-PC-05 rev.5, dated 10/4/2017), including research and corrective measures regarding the source of the contamination, in addition to the cause of non-detection by PCC1, in the event of an irregularity being detected.
Modification of the record for the application of corrective measures in the PCC1 check (RQ-PC-40 rev.1, dated 10/6/2017), with different sections for the causes of non-detection and the causes of the origin of the contamination.
Production managers and quality controllers are trained in this instruction.
The cause of faecal contamination or ingestion (detected in the check) shall be considered in the monthly trend study.

41/51 Ventilation:

During the walkthrough of the establishment the FSIS auditors' observed beaded condensation in multiple areas of the packaging room and in one area over exposed product; however there did not appear to be any dripping of condensation at the time of the observation. This product was not eligible for export to the United States.
It should be noted that during FSIS' pre-operational verification walkthrough of the slaughter area, MSSSI did identify areas overhead where condensation and moisture were not identified by the establishment.
In both instances the government officials took regulatory control to ensure exposed product and product contact surfaces were retained or rejected and that the establishment restored sanitary conditions. MSSSI will verify the establishment's additional measures to prevent the reoccurrence.

During the 2015 FSIS audit a similar deficiencies was identified relating to condensation. The establishment's previous corrective actions included multiple actions to address air flow and the development of a SPS program designed to monitor areas daily and take action when condensation is observed. These preventative measures do not appear to be effective at preventing reoccurrence.

FSIS auditors did identify that the establishment and MSSSI have identified deficiencies with ventilation - condensation. MSSSI's verification of actions taken by the establishment to prevent the reoccurrence of these types of deficiencies does not appear to be effective or have not been properly implemented by MSSSI

Corrective actions:

The inspectors documented a Record of Deficiencies in the application QUAESTOR Nº 20171998JFR. We obtain the immediate actions from the application and the long-term planned actions were verified with correct result by the Official Veterinary Services assigned to the establishment.

ESTABLISHMENT REPLY (Immediate Action(s)):
About the incident detected during Preoperational Control:
- 1.- Bleeding Area: Drip produced by a small hole in a steam pipe. We repair the pipe plugging the hole and recovering the pipe with a sheath. We attach Maintenance corrective record (NºPDS 17686 and 17687). We clean and disinfect the affected surface (tray for collecting the technical blood destined for non-human consumption).

- 2.- Red Offal's Inspection Point (Heard): Drip produced from leakage in a distribution valve of cold water that was not in service. It was located in the false ceiling. We solved plugging the valve. We clean and dry the roof in the affected area and also we clean and disinfect the trays and hocks for transporting the offal's. We attach Maintenance corrective record (NºPDS 17685).

- 3.- Offal's Processing area: Drip produced because of a clogging in the drain of refrigeration equipment. Immediately we proceed stopping the refrigeration equipment. We repair the clogging. We clean and disinfect the trays and hocks used for transporting the offal's. We attach Maintenance corrective record (NºPDS 17684 and 17688).

About the incident detected during the operational process:
- 1- Condensation in the roof of packaging area (area of entrance of wrapping line): We dry the roof and floor of affected area.

- 2- Condensation and Drip of the refrigeration equipment in the wrapping line area: We stopped the production of the line affected and we block the product that we were producing (in the box, in the line and the finished product) giving the following destination:

o The product from the box and packaging process is destined to be destroyed as category 3.

o Finished product: We do a complete microbiological analysis (4 test) to decide depending of the results de final destination.

We dry the pipe and the refrigeration equipment. We block the wrapping line affected to clean and disinfect the line and the packaging equipment. The line continues blocked all the day till solving definitely the drip on the refrigeration equipment.
After doing the investigation we define two reasons:
1.- The condensation on the roof and the refrigeration equipment is caused by the inadequate dried after the preoperational clean. We dry the surfaces and the condensation didn't appear again.
2.- The drip of the refrigeration equipment is caused by drain clogged. The refrigeration equipment have two trays with a sponge in the middle (ARMAFLEX). The clogging drain lead to accumulate water in the sponge and causing the drip.
At the end of the shift we repair the drain and we change the sponge Armaflex for a new one.
The shift after, before starting the production, we checked the absence of condensation and drip and we unlock the wrapping line. We attach Maintenance corrective record (NºPDS 17690, 17692 and 17793).

ESTABLISHMENT REPLY (Additional Action(s)):

- Decision about the destiny of blocked product: the results of the analysis done with the product are correct in the four test (we attach analysis report). We decide to set free the wrapped finished product.

- We modify the control process for detecting condensation to identify risk areas:

o Instructions and Training for detection of condensation for production line managers in the risk areas.

o Surveillance of the absence of condensation in the roof, refrigeration equipment and structures checked by the Quality Control in the preoperational control (before starting production) and at each pause during the operational control (4 daily checks). The areas where we detect condensation will be included in the risk areas list. It will be recorded every surveillance (we attach RQ-BP-11).

o Thermographic analysis in all the plant to detect thermic changes that could become in a condensation risk area. We have started with the packaging area.

- Updating of the Condensation Control Procedure (PQ-OF-01) including the new surveillance system.
- Inclusion in the Maintenance Plan the checking of all the drains of the refrigeration equipment every 3 month
- Evaluation monthly of the Condensation surveillance system and the corrective actions implemented.
- We move the refrigeration equipment of the packaging area to avoid having any production line below. We have installed on the corner separated of production lines and erasing the risk of contamination (to improve the air circulation, we will install textile pipes above the area). We área attaching a photo of new the location:

BEFORE

ACTUAL LOCATION

46/51 Sanitary Operations - Swine Carcasses:

During the walkthrough of the establishment FSIS auditors observed a 1-1 ½ in diameter black gel like substances (appeared to be rail lubricant) located on the medial/ posterior portion of the leg/ham area on 2 carcasses in the carcass cooler that were held for further processing.
The establishment failed to prevent the incidental contamination of carcasses with rail dust. These observations indicate ineffective maintenance and monitoring of overhead structures and verification of establishments SPS programs by CCA inspection personnel which are crucial to an establishment's ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.
In both cases, the government officials took regulatory control to ensure the carcasses were reprocessed to restore sanitary conditions and will verify establishment's additional measures to prevent the reoccurrence

Corrective Actions:

The inspectors documented a Record of Deficiencies in the application QUAESTOR Nº 20171999JFR. We obtain the immediate actions from the application and the long-term planned actions were verified with correct result by the Official Veterinary Services assigned to the establishment.

ESTABLISHMENT REPLY (Immediate Action(s)):
An expurgation is done to the 4 carcasses found with grease contamination.
The establishment has systems to avoid the grease contamination of the carcasses:
Weekly cleaning of the rails
Daily check of the rails lubrication
Cleaning of the hooks that hold the carcasses in continuous output with air and water, in the primary area, after the first flaming.
Collector brushes in the bottom part of the rail, at the evisceration line (permanent installation)
Green Teflon slider in different points at the evisceration line, in order to avoid grease accumulation (permanent installation)
The establishment has different points of control to identify and separate the carcasses with presence of grease from the transportation rails:
Production worker controlling the product in the evisceration line (diverts the carcasses to re-inspection for expurgation. Control records of the carcasses diverted for other reasons (RQ-PC-42), in section OTROS)
CCP-1 production workers (divert the carcasses to the side rail for its expurgation). It is not recorded.
Hygiene worker in the stabilization room (expurgates the carcasses from the rail where they are located). Control record of the grease on the rails at the classification room (RQ-ND-25).
Production worker in the first position of the cutting room entrance (back rib cut mark) (stops the entrance line of the carcasses and expurgates de contaminated parts. It is not recorded.
The establishment has a record for various hygiene deficiencies (POH, RQ-BP-11) in which it is contemplated the item: ausencia de contaminación cruzada en producto causada por sustancias contaminantes (POH-09). This record is done in continuous, by the quality controller, during the production.

ESTABLISHMENT REPLY (Additional Action(s)):
Modification of the PROCEDURE OF THE MEAT, VISCERA AND CARCASSES FALLEN ON THE FLOOR OR CONTAMINATED (PQ-PR-07) with the specific inclusion of the actions and corrective actions in case of contamination due to dripping or contact with lubrication grease.

New incidents record of the contaminated carcasses with grease, detected in the CCP and at the entrance of the cutting room. Modification of the record of the carcasses in the re-inspection.
Monthly investigation of the most risky points of grease contamination, evaluation and actions for a final solution.
The establishment has currently located two structures that may cause a grease accumulation on the rails and a possible carcass contamination:
The second section of the quick chill room (carcass refrigeration tunnel) has a traction system of the hooks by dragging, by a pusher, in which is necessary a lubrication of the rails, done every day before the production starts. In the rail curves it is necessary a more intense lubrication, which causes a grease accumulation and the possibility of cross contamination. It is under study the replacement of this traction system with a system of hanging hooks. As an intermediate solution, the Teflon material of the piece above the rails in the curves will be substituted, in order to improve the slip of the hooks and reduce the amount of lubricant.
The diverter pistons of the carcasses in the rails of the stabilization room keep part of the lubricating grease that drag the hooks which come from the quick chill room. The reduction of the lubricant usage (as the solution of the previous point) will decrease the accumulation of grease in the diverting points. In addition to that, it is planned to replace the Teflon material of the parts in the upper side of the deviation points, making the slip of the hooks easier, without needing lubricating grease.

ESTABLISHMENT Nº -37 PATEL S.A.

46/51 Sanitary Operations - Swine Carcasses

During the walkthrough of the establishment FSIS auditors observed black smears (appeared to be rail dust) on multiple carcasses located on the transfer rail leading into the carcass cooler as well as inside the cooler for pork carcasses that were held to be further processed.
The establishment failed to prevent the incidental contamination of carcasses with rail dust. These observations indicate ineffective maintenance and monitoring of overhead structures and verification of establishments SPS programs by CCA inspection personnel which are crucial to an establishment’s ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.
The government officials took regulatory control to ensure the carcasses were reprocessed to restore sanitary conditions and will verify establishment's additional measures to prevent the reoccurrence.

Corrective Actions :

The inspectors documented a Record of Deficiencies in the application QUAESTOR (2017 1992RRF . We obtain the immediate actions from the application and the long-term planned actions were verified with correct result by the Official Veterinary Services assigned to the establishment.

12. REPLY FROM THE ESTABLISHMENT (immediate action/s):

The output chain of the airing chamber was immediately stopped to clean the gearing of the chain and the grease stains on the carcasses affected.

13. REPLY FROM THE ESTABLISHMENT (Additional planned action /s):
The causes of this situation were studied and the conclusion was an excess of grease accumulated on the chain and guide due to the weekly lubrication, and the lack of elimination of

the excess grease/accumulated oil. The whole of the system of the chain of the airing chamber and the chain and guide of the carcass input in the cutting room is going to be cleaned immediately.
In order to avoid the excessive accumulation of grease/oil on these chains and guide, monthly cleaning is to be stipulated of the excess grease/oil of these areas. In order to assess whether this is the right frequency, a weekly check will be made of the state of the guide and chain greasing.

ANNEX 2

SPECIFIC COMMENTS

In relation to the audit report, we have some additional comments:

- Page 7 and 8:

The draft read: *The standard for the qualifications of official veterinarians is given by the selection processes described in Order Ministerial APA/1322/2008*

The mentioned ministerial order APA / 1322/2008 was an example of a selective process in 2008. According to the public employment offer, the regional authorities (CAs) and the central authority (ACC) call selective processes with certain regularity. The last example of these selective processes is the Resolution of April 17, of the Undersecretary of the Ministry of Health, Social Services and Equality, through which the selective process of veterinarians is convened.

- Page 18 :

The draft read: *The FSIS auditors verified that the CCA's implemented sampling protocol mandates test and hold practices (holding or controlling product until results become available) to ensure that MSSSI verifies acceptable residue results prior to issuing certification for export to the United States.*
Holding or controlling product until result became available is made in case of suspicious sampling for residues analyze. This is the case of carcass coming from farms with previous cases of detection of residues and it is under surveillance or in case the veterinary office decides to retain the product after ante-mortem or post-mortem inspection.