United States Department of Agriculture

Food Safety and
Inspection Service

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DEC 11 2019

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

Dear Dr. Vaquer,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Spain's meat inspection system from May 20 through June 5, 2019. 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 the Office of International Coordination, by electronic mail at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN SPAIN

MAY 20 THROUGH JUNE 5, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 20, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 20 through June 5, 2019. The purpose of the audit was to determine whether Spain's food safety inspection system governing raw and processed meat (fully-cooked, salt-cured, dried, and acidified/fermented) 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 - non intact; fully cooked - not shelf stable; not heat treated - shelf stable; and heat treated, but 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Central Competent Authority (CCA) inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g. INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The CCA does not require once per shift inspection coverage at High Pressure Processing (HPP) establishments, during pork processing operations, of product destined for export to the United States.
- The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The CCA's national chemical residue plan has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

During the audit exit meeting, the CCA committed to addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Spain's food safety system from May 20 through June 5, 2019. The audit began with an entrance meeting held on May 20, 2019 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, Consumer Affairs and Social Welfare (*Ministerio de Sanidad, Consumo y Bienestar Social* (MSCBS)). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure Spain's food safety inspection system governing raw and processed (fully-cooked, salt-cured, dried, acidified/fermented) 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 exports raw pork and further processed pork products to the United States:

Process Category	Product Category	Eligible Products
Raw - Non Intact	Raw ground, comminuted, or otherwise non-intact pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product
Raw - Intact	Raw intact pork	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Not ready to eat (NRTE) otherwise processed meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready to eat (RTE) acidified/fermented meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE dried meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE salt-cured meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	NRTE otherwise processed meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking)	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE dried meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE salt-cured meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE fully-cooked meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Pork - All Products Eligible
Heat Treated, but Not Fully Cooked - Not Shelf Stable	NRTE otherwise processed meat	Pork - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS), which regulates importation of animals and animal products into the United States, recognizes Spain as subject to the following restrictions: Beef and veal imported from Spain would be subject to foot-and-mouth disease (FMD) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) §94.11, but Spain is only exporting pork products to the United States; African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.31; swine vesicular disease requirements specified in 9 CFR 94.13; and bovine spongiform encephalopathy requirements specified in 9 CFR §94.18 and/or 9 CFR § 94.19.

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) reinspection and 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 the self-reporting tool (SRT).

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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, at three autonomous community regional offices, and at 11 local inspection (establishment) offices. The FSIS auditors evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors visited a sample of 11 establishments from a total of 26 establishments certified to export pork products to the United States. These included three slaughter and eight pork processing establishments. 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 could impact food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, FSIS audited one government microbiological laboratory and one government national reference chemical residue laboratory to verify the CCA's ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• MSCBS, Madrid
	Autonomous Communities (Regional)	3	• Andalusia Autonomous Community, Seville Regional Office • Extremadura Autonomous Community, Merida Regional Office • Valencia Autonomous Community, Valencia Regional Office
Laboratories		2	• Public Health Laboratory - Government Microbiological Laboratory, Girona • National Food Center - Government Chemical Residue Laboratory, Madrid
Pork slaughter establishments		3	• Establishment 28, Sociedad Cooperativa Valle de Los Pedroches, Pozoblanco • Establishment 34, Matadero Frigorifico de Fuentes el Navazo S.L., Fuentes de Bejar • Establishment 37, Patel S.A.U., Santa Maria Corco
Pork processing establishments		8	• Establishment 27, Embutidos Fermin S.L., Tamames • Establishment 29, Sociedad Cooperativa Valle de los Pedroches, Pozoblanco • Establishment 35, Senorio de Olivenza S.L., Olivenza • Establishment 40, Redondo Iglesias S.A.U., Quart de Poblet • Establishment 42, Sanchez Romero Carvajal Jabugo S.A., Jabugo • Establishment 43, Esteban Espuna S.A., Pobla de Lillet • Establishment 44, HPP Food Technology, Madrid • Establishment 45, Noel Alimentaria S.A.U., Olot

FSIS performed the audit to verify that Spain's food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); and
- The Food Safety and Inspection Service Regulations (9 CFR § 301 to the end).

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 Agreement on the Application of Sanitary and Phytosanitary Measures, 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. 1/2005;
- Regulation (EC) No. 396/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1881/2006
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 37/2010;
- Regulation (EC) No. 142/2011;
- Regulation (EC) No. 217/2014;
- EC Directive 93/119/EC;
- EC Directive 96/22/EC; and
- EC Directive 96/23/EC.

III. BACKGROUND

From February 1, 2016 to January 31, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 57,649,164 pounds of pork products exported by Spain to the United States. FSIS also performed additional types of inspection on 4,410,060 pounds of pork products, including laboratory testing for chemical residues and microbiological pathogens (e.g., *Listeria monocytogene*s (*Lm*) and *Salmonella*). As a result of these additional inspection activities, FSIS rejected 87,888 pounds of pork products for issues related to public health, including identification of *Lm* in 494 pounds of ready-to-eat (RTE) dried unsliced ham, and extraneous material in 9,609 pounds of raw - intact pork primals and subprimals. The remaining POE rejections were due to shipping container damage, certification, and labeling issues.

The previous FSIS audit conducted in 2017 identified the following finding:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g. INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The CCA and/or the in-plant government officials did not adequately verify 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 and/or in-plant government officials' inadequate verification of government sanitation requirements related to ventilation did not ensure that the establishment's corrective actions were effective at controlling condensation to prevent recurrence of noncompliance.

The FSIS auditors verified that the previously reported audit finding had been adequately addressed by the CCA.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Spain's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Spain's food safety inspection system governing pork products is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Spain's food safety inspection system are available on the FSIS website at: https://www.fsis.usda.gov/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 food safety 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.

Spain's administration of its food safety inspection system is organized into central, autonomous communities (ACs), and local inspection levels. At the central level, the overall responsibility for the organization and coordination of control systems is shared between two main ministries: 1) The Ministry of Agriculture Fisheries and Food (MAPA) whose responsibilities include animal health, animal welfare, animal feed, and primary production of food of animal origin, and 2) The MSCBS that serves as the CCA and is responsible for food safety. The Sub-directorate General of Foreign Health of the Directorate General for Public Health, Quality and Innovation is responsible for regulating inspection activities related to the export of pork products to the United States.

At the AC level, Spain is divided into 17 ACs and two autonomous cities of Ceuta and Melilla. The ACs' regional offices are responsible for enforcing regulatory requirements, overseeing in-plant inspection personnel activities, and providing official relief inspectors in case of planned or unplanned absences of official inspection personnel in establishments certified to export to the United States. The ACs' Veterinary Supervisors (VSs) provide direct supervisory authority over the establishments certified to export to the United States in accordance with the MSCBS'

requirements. The VSs are also responsible for conducting periodic supervisory reviews at the establishments certified to export to the United States.

At the local inspection level, the in-plant inspection personnel, Official Veterinarians (OVs), perform official controls and inspection activities continuously during slaughter operations and at least once per shift, with the exception of High Pressure Processing (HPP) establishments, during processing operations. The FSIS audit findings concerning inspection coverage at HPP establishments is discussed under Component Two of this report. The FSIS auditors reviewed documentation that showed government inspection personnel located at the CCA headquarters, ACs, and local inspection levels are full-time government employees who are paid by the Spanish government.

The FSIS auditors verified by document review and interviews that the in-plant inspection personnel possessed the educational credentials, training, and experience to carry out their assigned tasks. Since the last FSIS audit in 2017, the MSCBS has organized ongoing training programs for in-plant inspection personnel in the establishments certified to export to the United States. Training courses have covered such subjects as pathogen reduction/HACCP, sanitation, traceability, sampling methodology, and FSIS import requirements. The FSIS auditors interviewed in-plant inspection personnel to assess their knowledge, skills, and abilities in addition to reviewing their training records from 2017 to 2019. The FSIS auditor verified that ongoing training materials, including program updates in inspection-related issues and procedures, were adequate with no concerns noted.

The FSIS auditors confirmed that in-plant inspection personnel assigned to establishments certified to export to the United States have attended the ongoing trainings. The training participation records were adequate and proper documentation was maintained at all levels of authority. In addition, the FSIS auditors reviewed documentation that the VSs conduct the annual performance evaluations of in-plant inspection personnel in accordance with the MSCBS' requirements. The review of these documents did not raise any concern.

The FSIS auditors verified that the MSCBS has documented and maintained its legal authority and responsibility to certify, suspend, and/or withdraw export approval from establishments certified as eligible to export to the United States. There have not been any major changes in the MSCBS' approval process to certify establishments since the last FSIS audit in 2017.

The MSCBS is responsible for ensuring that adulterated or misbranded products are not exported to the United States. Spanish 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 FSIS auditors verified that inspection personnel were responsible for ensuring that FSIS import requirements were met in accordance with the MSCBS' instructions.

The OVs export verification activities included examination of product condition (type, volume, and source), review of associated documents including labeling and pre-shipment review records, review of all applicable laboratory testing results, and issuance of official meat inspection health certificates for transit of meat products. The final export health certificate is

issued and signed by MAPA's official personnel based on documentation provided by OVs. The FSIS auditors' document review identified the following finding:

- The CCA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.

The FSIS auditors verified that the MSCBS has the legal authority and responsibility to certify, de-certify, or take appropriate enforcement measures in establishments certified to export products to the United States. The FSIS auditors reviewed the MSCBS approval process for eligible establishments that apply to be designated as establishments certified to export to the United States. Following the submission of an establishment's application, the inspection personnel review and conduct an on-site inspection. The MSCBS has the authority to approve the application considering the results of the document review, on-site audits, and implementation of any applicable corrective actions.

The MSCBS enforcement measures may include taking regulatory control action, withholding actions, or suspension. The FSIS auditors reviewed a sample of noncompliance reports (NRs) generated by in-plant inspection personnel. The FSIS auditors noted that in-plant inspection personnel had identified deficiencies during pre-operational and operational verification activities and documented their findings in an NR. The in-plant inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditors reviewed documentation on a selection of open and closed NRs and determined that in-plant inspection personnel have adequately described noncompliances and verified the effectiveness of the establishment's corrective actions.

The MSCBS has adopted the European Union (EU) legislation pertaining to production of food of animal origin to ensure that the same set of laws, regulations, and policies are applied consistently to all food producing establishments. In addition, the MSCBS has adopted FSIS regulatory requirements to ensure uniform and standardized implementation of FSIS inspection requirements in all establishments certified to export to the United States. The MSCBS develops technical instructions concerning implementation of FSIS requirements and disseminates them to all levels of inspection through its website. The updated information or revised policies are discussed during coordination meetings with the ACs' inspection officials.

The FSIS auditors verified that the audited establishments have developed and implemented traceability and recall procedures in accordance with the MSCBS' requirements. The establishments' procedures provide written instructions that include traceability mechanisms to ensure source materials originate from establishments certified to export to the United States in eligible establishments or countries, separation from establishments not certified to export to the United States or ineligible products, and record keeping requirements. The in-plant inspection personnel verify the efficacy of these procedures during their inspection verification activities. The FSIS auditors reviewed in-plant inspection documented verification records and associated traceability records generated by establishment personnel. These documents met the MSCBS requirements and the FSIS auditors found no concerns. There has been no recall of products destined for export to the United States since the last FSIS audit in 2017.

The FSIS auditors confirmed that in-plant inspection personnel verify that raw meat products originate only from establishments certified to export to the United States. The FSIS auditors verified the source of raw products for further processing by cross-referencing transit certificates, bills of lading, and associated pre-shipment records that accompany each shipment of raw source materials. The FSIS auditors confirmed through interviews and record reviews that in-plant inspection personnel are verifying the proper implementation of the establishment's procedures separating the United States production operations from other markets by space or time.

The FSIS auditors noted that a network of government laboratories conduct analyses of meat products intended for export from Spain to the United States. All of these laboratories are accredited by the Spanish Accreditation Body (ENAC) in accordance with the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025, *General requirements for the competence of testing and calibration laboratories*. In addition to ENAC audits, the MSCBS also provides oversight by conducting annual audits of government microbiological laboratories. The FSIS auditors reviewed laboratory records and interviewed the laboratory analysts to assess their technical competency, training, and knowledge of the analytical methods.

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. However, the FSIS auditors noted that the inspection personnel are not required to review and confirm acceptable testing results from chemical residue samples of products tested for adulterants as defined by FSIS prior to signing the export certificate.

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 each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that the OVs conduct ante-mortem inspection on the day of slaughter in accordance with the MSCBS' ante-mortem requirements. The OVs observe all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter. The FSIS auditors observed and verified that all animals had access to water in all holding pens, and establishments had procedures to provide feed if animals are held for more than 24 hours. Each audited slaughter establishment maintained a designated holding pen for further examination of sick or suspect animals. The OVs document the results of ante-mortem

inspection examination, numbers of animals presented for slaughter, and number of animals condemned during either ante-mortem or post-mortem inspection examinations. The FSIS auditors verified that the OVs evaluate the establishment's compliance with humane handling and slaughter requirements for animals by performing daily verification of the MSCBS requirements that include corroboration of the loss of consciousness and accompanying indicative signs of adequate stunning before animals are shackled and bled.

The FSIS auditors reviewed the implementation of post-mortem inspection examinations through review of inspection records, interviews, and observations of post-mortem inspection activities in audited slaughter establishments. The FSIS auditors correlated the number of in-plant inspection personnel who conduct post-mortem inspection activities in each audited establishment with the maximum slaughter rate and concluded that the MSCBS has provided a sufficient number of inspection personnel for the existing production volume and slaughter line speed. However, the MSCBS did not have a written staffing standard based on species slaughter and line speeds to ensure sufficient staffing in the event that there is an increase in production volume in certified slaughter establishments eligible to export to the United States.

The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of each carcass and accompanying viscera are being implemented. The in-plant inspection personnel are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditors observed the performance of in-plant inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with the MSCBS' requirements.

The FSIS auditors verified that the control of condemned materials is accomplished through the application of the MSCBS' requirements. The FSIS auditors verified the proper application of these requirements including: (1) appropriate identification of inedible or condemned materials; (2) segregation in specially marked or otherwise secure containers; and (3) final documented disposal of these materials at proper facilities.

The FSIS auditors verified that in-plant inspection personnel perform official controls and inspection activities continuously during slaughter operations and at least once per shift during the processing of pork products destined for export to the United States, with the exception of the two HPP facilities. The FSIS auditors noted that the OVs are physically present in HPP facilities once a week and when required to sign transit certificates. However, the OVs are not required to be present during the HPP processing of products for export to the United States. The FSIS auditors identified the following findings:

- The CCA does not require once per shift inspection coverage at HPP establishments, during pork processing operations, of product destined for export to the United States.
- The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.

The FSIS auditors verified that the OVs' verification activities include direct observation and review of records related to implementation of sanitation performance standards, sanitation standard operating procedures (Sanitation SOP), HACCP, chemical residue and microbiological

sampling programs, and species verification testing. The MSCBS has developed specific risk-based verification frequencies for the OVs to conduct at each establishment certified to export to the United States. The ACs ensure the proper implementation and documentation of the assigned verification procedures at all establishments certified to export to the United States. The FSIS auditors verified through direct observation and review of records that the OVs performed the assigned verification activities in accordance with the MSCBS requirements.

The FSIS auditors accompanied and observed the function of the VSs responsible for conducting periodic supervisory reviews. During these reviews, the VSs verified the MSCBS' requirements for ante-mortem inspection; humane handling and slaughter requirements; post-mortem inspection; microbiological sampling; labeling; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the zero tolerance critical control point (CCP) verification in the audited establishments. Additionally, the VSs evaluate the knowledge, skills, and abilities of the OVs assigned to establishments certified to export to the United States on a yearly basis in accordance with the MSCBS' established procedures. The FSIS auditors reviewed the results of the documented periodic supervisory reviews and did not identify any concerns.

The FSIS auditors determined that the MSCBS has legal authority to establish regulatory controls over establishments certified to export to the United States. However, the FSIS auditors identified findings related to inspection coverage and implementation of hands-on pre-operational sanitation verification at HPP establishments. The MSCBS committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented.

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 Sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors verified that the MSCBS has adopted FSIS sanitation requirements consistent with 9 CFR § 416 requiring that establishments certified to export to the United States develop and implement Sanitation SOPs. The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each establishment's program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices.

The FSIS auditors confirmed that the OVs at establishments certified to export to the United States conduct verification of sanitary conditions in accordance with the *Inspection Procedures for Establishments Certified to Export to the United States*, 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 SOPs verification is set as daily for inspection personnel. The OVs entered sanitation

verification data into the QUAESTOR application, which can be analyzed by the MSCBS and AC inspection officials to detect trends of noncompliance. The FSIS auditors verified documentation that shows the verification frequency of sanitation requirements as they vary (yearly, monthly, weekly, and daily) and are scheduled in the establishment-specific annual Program of Inspection Procedures.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by shadowing and observing in-plant inspection personnel conducting pre-operational sanitation verification inspection. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The FSIS auditors determined that the in-plant inspection personnel conduct pre-operational sanitation verification in accordance with the MSCBS' established procedures, which needs to be modified for inspection pre-operational sanitation verification at the HPP establishments when producing product for export to the United States.

The FSIS auditors observed in-plant inspection personnel perform actual operational sanitation verification in all of the audited establishments. The FSIS auditors noted that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors compared their overall observation of the sanitary conditions of the establishments with the in-plant inspection verification records. The FSIS auditors' record review included both the establishments' sanitation monitoring and corrective action records; the in-plant inspection records documenting inspection verification results, and noncompliances; and periodic supervisory reviews of establishments. The FSIS auditors' review of records generated by in-plant inspection personnel (including noncompliance and verification records) showed that in-plant inspection personnel have identified and documented sanitation findings in QUAESTOR in accordance with the MSCBS requirements.

The FSIS auditors noted that the MSCBS requires sanitary dressing of livestock at slaughter establishments. As a result, each audited slaughter establishment has implemented sanitary procedures to prevent potential carcass contamination throughout the process. These include sanitary procedures to prevent carcass contamination between carcasses during dressing procedures and prevent carcass contamination with gastrointestinal contents during evisceration. However, the FSIS auditors documented, on the individual establishment checklists located in Appendix A of this report, inadequate operational sanitary dressing procedures in two of the three audited slaughter establishments.

The FSIS auditors verified that the audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. Establishment personnel responsible for the implementation and monitoring of the Sanitation SOPs correctly authenticated these records with initials or signatures and the date.

Isolated noncompliances related to the verification of sanitation requirements are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors' analysis and on-site verification activities indicate that the MSCBS requires operators of official establishments to develop, implement, and maintain sanitation programs. FSIS concludes that the MSCBS continues to meet the core requirements for this component.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (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.

Spain's meat inspection system follows EU requirements for establishments certified to export to the United States, Regulation (EC) Nos. 852/2004 and 854/2004, in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR § 417. Instructions for further implementing HACCP regulatory requirements in establishments certified to export to the United States are documented in *Inspection Procedures for Establishments Certified to Export to the United States* and *Regular Monitoring Procedures for Establishments Certified to Export to the United States*.

The FSIS auditors conducted an on-site review of each audited establishment's HACCP system, including hazard analysis, HACCP plans, and CCP monitoring records. The FSIS auditors verified that the establishments took appropriate corrective actions in response to any deviations from their critical limits. The FSIS auditors reviewed zero tolerance CCP records for feces, ingesta, and milk at three slaughter establishments and verified the physical CCP locations by observing inspection personnel conducting hands-on verification activities in accordance with the *Inspection Procedures for Establishments Certified to Export to the United States*. The OVs document their HACCP verification results in the QUAESTOR application. The FSIS auditors reviewed the OVs' HACCP verification records within QUAESTOR.

At the audited establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. The FSIS auditors noted that the establishments producing dry-cured pork products maintained validated HACCP programs to support a 5-log reduction for *Salmonella* in these products. Furthermore, it was determined that these establishments maintained the required sampling and testing programs for *Lm* and *Salmonella* for finished products and *Lm* for food-contact surfaces (FCS) and nonfood-contact surfaces (NFCS). The FSIS auditors reviewed the establishments' and government's verification testing programs and results for *Salmonella* in finished products.

The FSIS auditors identified isolated noncompliances related to the inspection verification of HACCP requirements. These findings are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors' analysis and on-site verification activities indicate that the MSCBS requires operators of establishments certified to export to the United States to develop, implement, and maintain a HACCP system for each processing

category. FSIS concludes that the MSCBS continues to meet the core requirements 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 food safety 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.

Prior to the on-site visit, FSIS residue experts reviewed Spain's national chemical residue control plan (*Plan Nacional de Investigación de Residuos* (PNIR)), the *National Plan for Official Control of the Food Chain* (PNCOCA) 2016-2020, the associated methods of analysis, and additional SRT responses outlining the structure of Spain's chemical residue testing program. As a member of the EU, Spain's chemical residue plan complies with EU standards. The MAPA and the MSCBS develop the PNCOCA in accordance with EC Directive 96/23/EC.

The PNCOCA provides the framework program for the official control of contaminants, pesticides, veterinary drug residues, and banned substances. Article 5 of EC Directive 96/23/EC mandates that each EU member country update its national residue control plan annually for the following year based on the results of the previous year in order to consider any changes in chemical group and detection measures. The PNIR, regulated by National Law Royal Decree 1749/98, specifies the analytes to be detected, the method of analysis to be used, the species, the matrix to be collected, the tolerance, the action level, and the total number of samples to be collected. The action levels in the PNIR are based on the maximum residue limits in Regulation (EC) No. 37/2010 for veterinary drugs, Regulation (EC) No. 396/2005 for pesticides, and Regulation (EC) No. 1881/2006 for heavy metals and dioxins.

National Law Royal Decree 1749/98 provides specific procedures for addressing violative test results. This includes specific instructions for reporting of test results to inspection personnel, product sequestration, on-farm investigation, follow-up sampling of animals from the same producer. The FSIS auditors' document review identified the following finding:

- The CCA's national chemical residue plan has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

The FSIS auditors verified that in-plant inspection personnel who collect the residue samples are following the MSCBS' sampling protocol. This protocol includes sampling methodology, identification of animals, sampling frequency, traceability, and secure delivery of residue samples to designated laboratories. A review of the sampling records maintained at the audited establishments indicated that the 2019 sampling program was being implemented as scheduled.

The FSIS auditor visited the National Food Center (*Centro Nacional de Alimentación*); the national reference laboratory accredited to ISO/IEC 17025 standards by ENAC to analyze chemical residues samples as part of Spain's PNIR sampling plan. The FSIS auditors reviewed ENAC's most recent audit report and verified the proper implementation of corrective actions in response to the identified noncompliances. The FSIS auditors did not identify any concerns.

There have not been any POE violations related to this component since the last FSIS audit in 2017. The FSIS auditors' analysis and on-site audit verification activities indicate that the MSCBS continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

Prior to the on-site audit, FSIS microbiologists reviewed Spain's national microbiological sampling and testing programs, laboratory methods of analysis, and additional SRT responses outlining the structure of the MSCBS' microbiological verification sampling and testing programs.

The FSIS auditors verified that all three audited pork slaughter establishments conduct *Enterobacteriaceae* and Total Viable Count (Aerobic Plate Count) sampling and testing in accordance with the *Official Microbiological Verification Program in Slaughterhouses* and Regulation (EC) No. 2073/2005 to verify process control. *Enterobacteriaceae* testing has been accepted as equivalent to generic *Escherichia coli* by FSIS. The FSIS auditors reviewed the establishments' testing results showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. The FSIS auditors reviewed the establishments' records and observed the establishments' employee sample collection methodology in one of the audited slaughter establishments. No concerns arose because of these observations and reviews.

The FSIS auditors verified that the MSCBS has a *Salmonella* sampling and testing program in raw product in accordance with *Official Microbiological Verification Program in Slaughterhouses* and Regulation (EC) No. 217/2014. The FSIS auditors reviewed the implementation of the program in the three audited slaughter establishments along with results and records documenting performance standards. The FSIS auditors verified that in-plant inspection sample collection methodology is in accordance with the MSCBS sample collection protocols.

The FSIS auditors reviewed records, including *Salmonella* spp. results, and observed the OVs' sample collection methodology in one of the audited slaughter establishments. No concerns arose because of these observations and reviews.

The FSIS auditors verified that the MSCBS has implemented official ongoing verification testing programs for *Salmonella* in RTE products and *Lm* in RTE products, FCS, and NFCS. The FSIS auditors noted that the MSCBS had adopted and implemented FSIS regulatory requirements related to the control of *Lm* in the post-lethality RTE environment of the processing establishments as outlined in 9 CFR § 430. Accordingly, the MSCBS requires RTE processing establishments that produce post-lethality exposed product to control *Lm* by adopting one of the three alternatives in a manner consistent with 9 CFR § 430.4. The MSCBS regulatory microbiological verification program *Official Microbiological Verification Program in RTE Food Production Lines (sampling in product, FCS, and NFCS)* adopts the zero tolerance approach for *Lm* and *Salmonella* in RTE pork products and considers an RTE product adulterated when the product comes in direct contact with an FCS contaminated with *Lm*.

The in-plant inspection personnel collect official verification samples, and the designated government microbiology laboratories conduct analysis using the FSIS Microbiology Laboratory Guidebook or other equivalent methods. The FSIS auditors verified that in-plant inspection personnel review and confirm acceptable testing results from all samples of products (i.e., establishment testing and government verification testing) tested for adulterants as defined by FSIS prior to signing the export certificate. If the RTE product tests positive for either *Lm* or *Salmonella,* it is not eligible for export to the United States. The FSIS auditors' interviews and document reviews in relation to *Lm* and *Salmonella* microbiological testing programs for RTE products did not identify any issues.

The FSIS auditors visited the Public Health Laboratory, a government microbiological laboratory, in Girona. The FSIS auditors verified that ENAC has accredited the laboratory in accordance with ISO/IEC 17025:2005 standards. The MSCBS and ENAC conduct an annual technical review of this laboratory in support of the approval process. During the laboratory visit, the FSIS auditors reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analyst training, equipment calibration, media preparation and storage, and reporting of results. The FSIS auditors did not identify any deficiencies.

Since the last FSIS audit in 2017, FSIS has reported one microbiological (*Lm*) POE violation, dated August 26, 2018, in imported RTE Iberico ham products. FSIS accepted the MSCBS' proffered corrective actions to address the POE violation. The FSIS auditors audited the producing establishment and verified that the corrective actions described in the MSCBS' response were implemented.

The FSIS auditors' analysis and on-site verification activities indicate that the MSCBS continues to maintain the legal authority to implement its microbiological sampling and testing programs to ensure that meat products are safe and wholesome. FSIS concludes that the MSCBS continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 5, 2019, in Madrid, Spain, with the MSCBS. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The CCA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g. INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The CCA does not require once per shift inspection coverage at HPP establishments, during pork processing operations, of product destined for export to the United States.
- The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The CCA's national chemical residue plan has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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
Embutidos Fermin S.L. . Tamames	05/22/2019	27	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	X
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	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

15: Establishment identified a microbiological hazard as being reasonably likely to occur in their Not Heat-Treated Shelf Stable Hazard Analysis but did not develop a critical control point. In their justification, they stated that low water activity controlled the microbiological hazards but did not reference a program that addressed water activity. The establishment verbally explained that they receive documents from the producing establishments verifying the water activity is below 0.92.

15: Establishment listed three critical control points (CCP1=thermal treatment, CCP2= thermal treatment, and CCP3= HPP) to control microbiological hazards in deboned and sliced product but some products were controlled with CCP1, some products were controlled with CCP2, some products were controlled with CCP1 and CCP2, and some products were controlled with CCP3. The hazard analysis and HACCP plan did not justify why the biological hazards in products are controlled with different CCPs. For example, products controlled with CCP3 (HPP) are not controlled with CCP1 or CCP2. The establishment's Hazard Analysis and HACCP plans do not indicate which products should be controlled with the different CCPs for microbiological hazards.

45: Dirty equipment surfaces above packaged RTE products destined for slicing.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/22/2019

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
Sociedad Cooperativa Valle de los Pedroches Cordoba	05/29/2019	28	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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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	
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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/20/2019

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
Sociedad Cooperativa Valle de los Pedroches Pozoblanco	05/30/2019	29	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	
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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. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/30/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Matadero Frigorifico de Fuentes El Navazo S.L. Fuentes de Bejar	05/23/2019	34	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

20: Establishment conducts 100% visual monitoring for zero-tolerance of fecal, ingesta and milk. On the day of the FSIS audit, the establishment slaughtered 3,924 pigs and documented 150 incidents of fecal or ingest contamination. The auditor reviewed zero-tolerance failures for the month of April 2019 and the daily number was consistent with the number documented on the day of the audit. The establishment does not perform corrective actions for each zero-tolerance deviation other than carcass disposition. At the end of the shift, they summarize the likely cause for all the zero-tolerance deviations. The documented causes of the deviations are the same: the producers did not adhere to withholding periods due to animals being free range and/or employee poor handling practices. Their preventative measures consist of regularly sending letters to producers informing them of the increased amount of contamination due to their lack of adherence to the withholding periods and training employees once a year.

46: Establishment did not maintain adequate separation of carcasses and hooves during processing.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/23/2019

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
Senorio De Olivenza S.L.. Badajoz	05/28/2019	35	Spain
	5. AUDIT STAFF: OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

15: The establishment's flow chart includes parameters that are part of a prerequisite program but do not address the prerequisite program in their hazard analysis.

15: The establishment’s hazard analysis identifies metal as a physical hazard in sliced product but does not identify the basis for metal being a hazard or why metal is only a hazard in sliced product.

38: There were multiple dead flies in a drying (curing) room with U.S. product and in the storage room for supplies. An open non-compliance regarding pest control was documented by the OVS on 05/14/19.

39: In the slicing room for RTE products, the auditor observed a 2-3 inch opening along the wall seam and dripping from a hose attached to the slicing machine. The establishment had documented the 2-3 inch wall opening three months earlier but had not taken steps to address it.

39: In the deboning area for RTE cured hams and shoulders there were cracked, pitted or inadequately sealed wall coverings.

45: In the deboning area for RTE cured hams and shoulders there were frayed plastic food contact boards on the molding machine and peeling of labels on the equipment.

45. In the deboning area for RTE cured hams and shoulders, there were dirty and frayed fabric straps used to raise and lower outside window shades. These straps were made of material that does not facilitate thorough cleaning. Additionally, the establishment does not include these straps in their sampling program for RTE environments. During the walk through, the in-plant inspector performed sampling on one of the fabric straps to test for *Listeria monocytogenes.*

46: In the deboning area for RTE cured hams and shoulders there were open windows with screens. The establishment does not include the window screens in their cleaning or sampling program for RTE environments.

46: In the deboning area for RTE cured hams and shoulders there was buildup of filth around the electrical plugs.

46: In the deboning area for RTE cured hams and shoulders there was mold and product debris in difficult to clean areas of the molding machine.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/28/2019

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. Santa Maria Corco	05/23/2019	37	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22: The establishment's HACCP verification records (direct observation or record review components) did not include the time of verification activities.

39: FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.

46: There was not adequate space between hoisted/eviscerated swine carcasses on the main slaughter line, therefore, swine carcasses with pathology or dressing defects could touch other carcasses. This may create insanitary condition or a potential for cross-contamination between carcasses.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/23/2019

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.U. . Quart de Poblet	05/29/2019	40	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/29/2019

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
Sanchez Romero Carvajal Jabugo S.A. Jabugo	05/31/2019	42	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/31/2019

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
Esteban Espuna Pobla de Lillet	05/24/2019	43	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

22: The establishment's HACCP verification record (record review component) did not include the time of the verification activities.

39: FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/24/2019

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
HPP Food Technology . Getafe	05/21/2019	44	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	X
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	X
51. Periodic Supervisory Reviews	
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. Review and Observation for Pre-Operational SSOP	X
58.	
59.	

60. Observation of the Establishment

20: During review of the corrective actions after a deviation from an established critical limit, the FSIS auditor noted that on multiple occasions, the establishment identified the cause of the deviation, but did not correct the cause of the deviation; instead, they documented the product disposition as the action taken to correct the cause of the deviation.

50: The CCA does not require once per shift inspection coverage at High Pressure Processing (HPP) establishments during processing operations of product destined for export to the United States.

57: The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/21/2019

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
Noel Alimentaria, S.A.U. Olot	05/22/2019	45	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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	
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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	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. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

22: The establishment's HACCP verification record for calibration of monitoring instruments (pH meter) did not include the actual value or the time of verification activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/22/2019

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

MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

SECRETARÍA GENERAL DE SANIDAD Y CONSUMO

DIRECCIÓN GENERAL DE SALUD PÚBLICA, CALIDAD E INNOVACIÓN

SUBDIRECCIÓN GENERAL DE SANIDAD EXTERIOR

Michelle Catlin, PhD

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

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

Madrid, October 10, 2019

In relation to the audit report related to the audit carried out from May 20 to June 5, 2019 in Spain, and received last September 3, we do not have general comments.

Regarding the systemic findings, we inform you that corrective actions have been already adopted. Attached to this letter (appendix I) you will find details about the actions taken.

In relation to the specific findings of the establishments, we will send the actions taken in a following letter according to the given timeframe of 60 days.

Sincerely,
Fernando Carreras Vaquer
General Deputy General Director

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL
DIRECCIÓN GENERAL DE SALUD PÚBLICA, CALIDAD E INNOVACIÓN
SUBDIRECCIÓN GENERAL
DE SANIDAD EXTERIOR

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

APPENDIX I

In relation to the system findings, the following actions have been taken:

GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

- The CCA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.

During the time of the Audit, the Spanish authorities had already published a draft procedure that established the review of the results of residues before the issuance of the export certificates. As this written procedure was not yet implemented, FSIS documented this finding as a systemic finding. After the FSIS audit, on 06/12/2019 the Deputy General Directorate for Foreign Health held a meeting with all the establishments authorized to export to the U.S and with the official competent authorities (Autonomous Communities).The objective of this meeting was to provide information about the to the actions for the entry into force of the procedure . The "Pre-shipment review procedure in authorized US establishments" (version 0 of 06/24/2019) has come into force on 07/15/2019. This procedure has already been sent to FSIS in the 2019 Self-Reporting Tool (SRT) and it is available in PHIS application. Nevertheless, below is attached a link for your information:

http://www.mscbs.gob.es/profesionales/saludPublica/sanidadExterior/docs/PreenvioFinal062019.pdf

With this procedure, MSCBS has established conditions that warrant the "retention and testing" principle. Any lot intended to be exported to the U.S, will not be exported until the results are obtained.

To reinforce the guidelines and official control activities that IPP perform, an additional meeting was held in MSCBS on 09/12/2019 with inspectors and supervisors. The objective of this meeting was to review the main aspects and clarify specific problems in the application of the procedure. The procedure includes in section 5.5 those cases in which a nonconformity is documented to the establishments and in section 5.6 those cases in which enforcement actions will be taken.

Finally, the correct application of this procedure includes the evaluation of the individual performance of the inspectors according to the official control supervision procedure.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G. INSPECTION SYSTEM OPERATION, PRODUC STANDARDS AND LABELING, AND HUMANE HANDLING)

- The CCA does not require once per shift inspection coverage at HPP establishments, during pork processing operations, of product destined for export to the United States.

After the FSIS audit, the Deputy General Directorate for Foreign Health sent a letter dated on 10/06/2019 addressed to the Autonomous Communities of Madrid and Catalonia where the establishments that apply high hydrostatic pressures treatments (HPP) are placed (establishments No. 38 and No. 44). In this letter, they have been informed about the obligation of the presence of the inspector every time a U.S batch is produced. Therefore, this requirement is already in force.

After the letter, the 2 Autonomous Communities have introduced the necessary modifications to comply with this requirement.

- The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.

Similar to the previous case, in the letter of 10/06/2019 sent to the Autonomous Communities where the HPP establishments are located, it was indicated that although they received packaged products, this condition does not exclude the performance of preoperational controls.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The CCA´s national chemical residue plan has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment´s request; however, the FSIS auditors´ review of records indicated that no retesting occurred on product shipped to the United States in recent history.

To respond to this systemic finding, a general principle of not elegibility for exporting to the US will be applied after the initial analysis (section c) according to point 5.1 of the Pre-shipment Review Procedure for U.S authorized establishments (see page 6). As we have already mentioned, this procedure is available in the PHIS application.

MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

SECRETARÍA GENERAL DE SANIDAD Y CONSUMO

DIRECCIÓN GENERAL DE SALUD PÚBLICA, CALIDAD E INNOVACIÓN

SUBDIRECCIÓN GENERAL DE SANIDAD EXTERIOR

Michelle Catlin, PhD

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

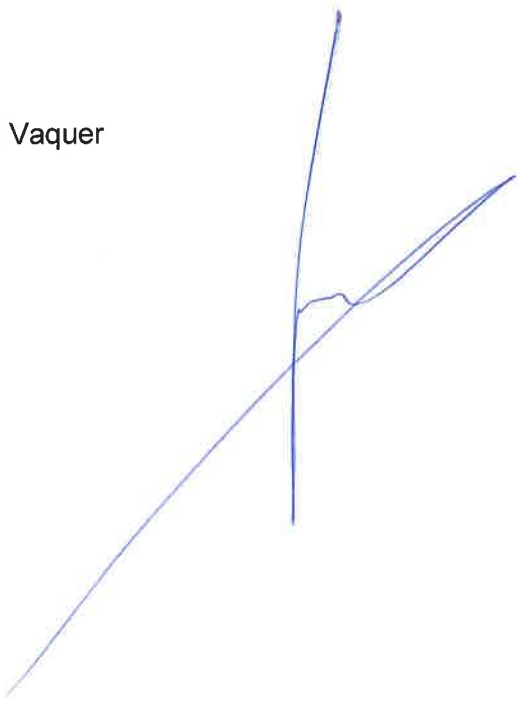
1400 Independence Avenue, SW.
Washington, D.C.
20250

Madrid, November 8, 2019

Dear Ms Catlin,

In relation to the specific findings observed during the audits carried out in Spain (between May 20 to June 5 2019), further to our previous letter of October 10, please find below the actions taken in the establishments, where you may check that all the deficiencies have been corrected.

Sincerely,
Fernando Carreras Vaquer



ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
EMBUTIDOS FERMÍN S.L. Tamames	**27**	**15.** Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	**15**: The establishment identified a microbiological hazard as being reasonably likely to occur in their Not Heat-Treated Shelf Stable Hazard Analysis but don´t reference a program that addressed water activity. The establishment verbally explained that they received documents from the producing establishments verifying the water activity is below 0.92.	Establishment has documented in the hazard analysis that they received Aw and other analysis from producing establishment.
			15: The establishment listed three critical control points (CCP1=thermal treatment, CCP2= thermal treatment, and CCP3=HPP) to control microbiological hazards in deboned and sliced product but some products were controlled with CCP1, some products were controlled with CCP2, some products were controlled with CCP1 and CCP2, and some products were controlled with CCP3. The hazard analysis and HACCP plan don´t justify why the biological hazards in products are controlled with different CCPs. For example, products controlled with CCP3 (HPP) aren´t controlled with CCP1 or CCP2. The establishment´s Hazard Analysis and HACCP plans do not indicate which products should be controlled with the different CCPs for microbiological hazards.	The flowcharts and management tables of PCC have been modified, being in force HACCP plan (31 Ed, 06/25/19) The sliced products were controlled with CCP3B (HPP), PCCs 1B and 2B, heat treatment, is not applied, because this product will be HPP treated (PCC 3B)
		45. Equipment and utensils	**45**. Dirty equipment surfaces above packaged RTE destined for slicing.	The dirty equipment surfaces (wheels of container) were cleaned and, in order to prevent contamination, before stacking containers, the products are protected with a plastic. Furthermore, a poster to announce and remember that the containers should be completely cleaned when the product is removed from them has been placed. This measure will be supervised by the Quality Department, to verify that it is done correctly.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
MATADERO FRIGORÍFICO DE FUENTES EL NAVAZO, S.L. Fuentes de Bejar	**34**	**20.** Corrective action written in HACCP plan.	**20:** The establishment conducts 100% visual monitoring for zero-tolerance of fecal, ingest and milk. On the day of the FSIS audit, the establishment slaughtered 3,924 pigs and documented 150 incidents of fecal or ingest contamination. The auditor reviewed zero-tolerance failures for the month of April 2019 and the daily number was consistent with the number documented on the day of the audit. The establishment does not perform corrective actions for each zero-tolerance deviation other than carcass disposition. At the end of the shift, they summarize the likely cause for all the zero-tolerance deviations. The documented causes of the deviations are the same: the producers did not adhere to withholding periods due to animals being free range and/or employee poor handling practices. Their preventative measures consist of regularly sending letters to producers informing them of the increased amount of contamination due to their lack of the withholding periods and training employees once a year.	The establishment has reassessed their HACCP plan including the CCP of zero-tolerance of fecal, ingest and milk. The establishment analyse the cause of the deviation individually and depending on the cause. Apart from the carcass disposition, different corrective actions can be applied depending of the cause: - In the case of animals arriving to the slaughterhouse without respecting the holding periods, a letter is sent to the owner of the farm of origin. - A new equipment to seal the rectum is prepared in case one of them stops running adequately during the slaughter. - In case of poor handling practices, training activities are carried out by the quality department to employees involved After the implementation of these measures to prevent recurrence, monitoring activities show that CCP deviations have decreased from 2% in April to an average of 0.3% during the last five months.
		46. Sanitary Operations	**46:** The establishment did not maintain adequate separation of carcasses and hooves during processing.	From the same day of the FSIS audit, the carcasses are placed with the hooves positioned outward to avoid contact between the hooves and the parallel half-carcass. Additionally, the establishment proceeded to the opening of the tracks where carcasses are hung to increase the distance between them. During operations, hooves from one carcass are not in contact with the previous or the subsequent carcass any more.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
PATEL S.A.U. Santa María Corco	**37**	**22.** Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	22: The establishment´s HACCP verification records (direct observation or record review components) didn´t include the time of verification activities.	The inspector notified the evaluators of the introduction of the time at which they perform the documentary verification, in addition to the date, initials and signature
		39. Establishment Construction/Maintenance	39: FSIS auditor observer numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.	The inspectors have verified the repair of the affected structures.
		46. Sanitary Operations	There was not adequate space between hosted/eviscerated swine carcasses on the main slaughter line; therefore, swine carcasses with pathology or dressing defects could touch other carcasses. This may create insanitary condition or a potential for cross-contamination between carcasses.	Modify the operation of the Automatic disc machine so it doesn´t saw totally the carcasses in two parts and leave them joined by the head. Install a piston to reduce the space between the two hooks that hold the carcasses by the feet, so that the distance between carcasses increases and the contact between them in the curve after the Automatic disc machine is not produced. Move the stainless-steel wall of Automatic disc machine, so that the contact of the carcasses with this wall is avoided. Do not separate the carcasses in two half carcasses until the veterinarian inspection point.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
ESTEBAN ESPUÑA Pobla de Lillet	**43**	**22.** Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	**22:** The establishment´s HACCP verification record (record review component) didn´t include the time of the verification activities.	The inspector notified the evaluators of the introduction of the time at which they perform the documentary verification, in addition to the date, initials and signature. Modifying the version of the records of pasteurization, the cooling of cooked products and the metal detector.
		39. Establishment Construction/Maintenance	**39:** FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.	The inspector documented that the holes identified were properly covered as well as the silicone remains.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
HPP FOOD TECHNOLOGY Getafe	**44**	**20.** Corrective action written in HACCP plan.	**20:** During review of the corrective actions after a deviation from an established critical limit, the FSIS auditor noted that on multiple occasions, the establishment identified the cause of the deviation, but did not correct the cause of the deviation; instead, they documented the product disposition as the action taken to correct the cause of the deviation.	The version of the production record - back side for incidents - is improved and updated to make it easier for the person who completes it to identify the elimination of the cause. Internal training is carried out to transmit the incident found to the staff, explain the new format and avoid recurrence in other formats in relation to the CCP.
		50. Daily inspection Coverage.	**50:** The CCA does not require once per shift inspection coverage at High Pressure Processing (HPP) establishments during processing operations of product destined for export to the United States.	After the FSIS audit, the Deputy General Directorate for Foreign Health sent a letter dated on 10/06/2019 addressed to the Autonomous Communities of Madrid and Catalonia where the establishments that apply high hydrostatic pressures treatments (HPP) are placed (establishments No. 38 and No. 44). In this letter, they have been informed about the obligation of the presence of the inspector every time a U.S batch is produced. Therefore, this requirement is already in force
		57. Review and Observation for Pre-Operational SSOP.	**57:** The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.	Similar to the previous case, in the letter of 10/06/2019 sent to the Autonomous Communities where the HPP establishments are located, it was indicated that although they received packaged products, this condition does not exclude the performance of preoperational controls

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
NOEL ALIMENTARIA, S.A.U. Olot	**45**	**22.** Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	**22:** The establishment´s HACCP verification record for calibration of monitoring instruments (pH meter) did not include the actual value or the time of verification activities.	The inspector documented that the daily calibration record of the pH measuring equipment has been reviewed, including the input of the time at which the equipment is calibrated and the values obtained. As well as an internal training activity of the new registry revision.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
SEÑORÍO DE OLIVENZA, S. L. Badajoz	**35**	**15.** Contents of the HACCP list the food safety hazards critical control points, critical limits, procedures corrective actions.	**15:** The establishment´s flow chart includes parameters that are part of a prerequisite program but don´t address the prerequisite program in their hazard analysis.	A new edition of the HACCP plan has been verified by establishment No. 35. After the review of the hazard analysis, this new version includes control points included in the prerequisite programs such as salting time
			15: The establishment´s hazard analysis identifies metal as a physical hazard in sliced product but does not identify the basis for metal being a hazard or why metal is only a hazard in sliced product.	The establishment has reviewed the hazard analysis. Last version identifies the reason why it is not necessary the use of the metal detector in the case of the whole pieces. For these products, the likelihood of physical danger is low.
		38. Establishment Grounds and Pest Control.	**38:** There were multiple dead flies in a drying (curing) room with U.S. product and in the storage room for supplies. An open non-compliance regarding pest control was documented by the OVS on 05/14/19.	The establishment has verified the condition and integrity of all the physical protection and insulation elements that prevent the entrance of flies. Furthermore, the proper functioning of the insect control devices has been checked. These actions are supported by documented procedures and working instructions.
		39. Establishment Construction/Maintenance.	**39:** In the slicing room for RTE products, the auditor observed a 2-3 inch wall seam and dripping from a hose attached to the slicing machine. The establishment had documented the 2-3 inch wall opening three months earlier but had not taken steps to address it.	It has been verified that the damaged items have been repaired.
			39: In the deboning area for RTE cured hams and shoulders there were cracked, pitted or inadequately sealed wall coverings.	All the wall coverings in the deboning room have been repaired and sealed adequately

		45. Equipment and utensils.	**45:** In the deboning area for RTE cured hams and shoulders there were frayed plastic food contact boards on the molding machine and peeling of labels on the equipment.	It has been verified that equipment and utensils are maintained in sanitary conditions. Deteriorated parts have been removed
			45: In the deboning area for RTE cured hams and shoulders, there were dirty and frayed fabric straps used to raise and lower outside window shades. These straps in their sampling program for RTE environments. During the walk through, the in-plant inspector performed sampling on one of the fabric straps to test for Listeria monocytogenes.	At first, official samples were taken for the investigation of Listeria monocytogenes on these non-contact surfaces (straps). Eventually, the straps of the deboning area were removed.
		46. Sanitary Operations.	**46:** In the deboning area for RTE cured hams and shoulders there were open windows with screens. The establishment does not include the window screens in their cleaning or sampling program for RTE environments.	In SSOP procedures, it has been documented an instruction regarding the closing and opening of the windows. This item is checked in the operational controls
			46: In the deboning area for RTE cured hams and shoulders there was buildup of filth around the electrical plugs.	The filth around around the electrical plugs was cleaned. This item has been included in the SSOP documented procedures.
			46: In the deboning area for RTE cured hams and shoulders there was mold and product debris in difficult to clean areas of the molding machine.	The equipment distribution in the deboning area for RTE products has been modified in order to improve the effectiveness of cleaning and sanitizing operations and to facilitate the inspection. As part of the SSOP documented procedures, the establishment has included the disassemble of the equipment before cleaning operations.