United States Department of Agriculture

Food Safety and
Inspection Service

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

Dr. Fernando Riesco Rodríguez
Subdirector General
Subdirección General de Sanidad Exterior
Ministerio de Sanidad, Política Social e Igualdad
Paseo del Prado 18-20
28014 Madrid, Spain

Dear Dr. Riesco Rodríguez,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Spain's inspection system July 8–31, 2024. 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 at InternationalCoordination@usda.gov.

Sincerely,

MARIA ESTERAS ORTIZ

Digitally signed by MARIA ESTERAS ORTIZ
Date: 2024.12.19 13:39:31 -05'00'

for:
Margaret Burns Rath, JD, MPH
Assistant Administrator
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

SPAIN

JULY 8–31, 2024

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED PORK, LAMB, SHEEP, AND GOAT PRODUCTS

INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

December 17, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Spain conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) July 8–31, 2024.

There were two audit objectives, the first of which was to verify that Spain's food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Spain currently exports the following categories of pork products to the United States: raw - intact; raw - non intact, comminuted, or otherwise non-intact; ready-to-eat (RTE) acidified/fermented (without cooking); RTE dried; RTE salt-cured; and not RTE otherwise processed.

The second objective was to verify Spain's food safety inspection system for raw lamb, sheep, and goat is being implemented as documented in the Self-Reporting Tool (SRT) and is functioning in a manner equivalent to that of the United States, producing products which are safe, wholesome, unadulterated, and correctly labeled and packaged. Although not currently eligible to export products from these species, Spain has recently updated its SRT submission with the intent to expand its export eligibility to include these types of products.

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 finding:

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

- An official government microbiological laboratory, the Regional Laboratory of the Autonomous Community of La Rioja, was not properly documenting the sample analysis procedure for detection of *Salmonella* and *Listeria monocytogenes* (*Lm*) in RTE pork products in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubator during various phases of analysis.

During the audit exit meeting, the CCA committed to address the preliminary finding 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.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Spain's food safety inspection system July 8–31, 2024. The audit began with an entrance meeting July 8, 2024, in Madrid, Spain, during which the FSIS auditors discussed the audit objectives, scope, and methodology with representatives from the Central Competent Authority (CCA) – Ministry of Health (MSAN). Representatives from MSAN accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted July 31, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

There were two audit objectives, the first of which was to verify that Spain's food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Spain currently exports the following categories of pork products to the United States: raw - intact; raw - non intact, comminuted, or otherwise non-intact; ready-to-eat (RTE) acidified/fermented (without cooking); RTE dried; RTE salt-cured; and not RTE otherwise processed.

The second objective was to verify Spain's food safety inspection system for raw lamb, sheep, and goat is being implemented as documented in the Self-Reporting Tool (SRT) and is functioning in a manner equivalent to that of the United States, producing products which are safe, wholesome, unadulterated, and correctly labeled and packaged. Although not currently eligible to export products from these species, Spain has recently updated its SRT submission with the intent to expand its export eligibility to include these types of products.

Spain is eligible to export the following categories of products to the United States.

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Not 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 - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible

USDA's Animal and Plant Health Inspection Service (APHIS) subjects' pork imported from Spain to African swine fever requirements specified in Title 9 of the U.S. Code of Federal Regulations (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 foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Spain's SRT responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Spain's food safety inspection systems governing raw and processed pork, lamb, sheep, and goat products are being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from MSAN through the 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.

The FSIS auditors reviewed administrative functions at MSAN headquarters, four regional offices, and 12 local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

A sample of 10 establishments was selected from a total of 29 establishments currently certified to export to the United States. This included four pork slaughter establishments, six pork processing establishments, and one pork processing/cold storage facility. The products these establishments produce and export to the United States include raw - intact pork; raw - non intact, comminuted, or otherwise non-intact pork; RTE acidified / fermented meat (without cooking); RTE dried meat; RTE salt-cured meat; and not RTE otherwise processed meat. In addition, two establishments which slaughter and process lamb, sheep, and goat (ovine and caprine) were included in this onsite audit to verify that Spain's food safety inspection system governing these species is being implemented as documented in the SRT and is functioning in a manner equivalent to that of the United States.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed MSAN's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also visited two laboratories to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Ministry of Health, Madrid
	Regional	4	• La Rioja Regional Department of Health, located in Logroño • Aragón Regional Department of Health, located in Zaragoza • Andalucía Regional Department of Health, located in Sevilla • Castilla y León Regional Department of Health, located in Valladolid
Laboratories		2	• Regional Laboratory of the Autonomous Community of La Rioja, microbiology section, located in Logroño • Aragón Public Health Laboratory, chemical residue section, located in Zaragoza
Swine slaughter and processing establishments		4	• Establishment No. 49, Cárnicas Cinco Villas S.A.U., Ejea de los Caballeros • Establishment No. 33, Frigoríficos Costa Brava S.A., Girona • Establishment No. 37, Patel S.A.U., Santa Maria de Corcó • Establishment No. 48, Jamones y Embutidos JAEM, S.A., Villar de Gallimazo
Ovine and caprine slaughter and processing establishments		2	• Establishment name, Moralejo Selección, S.L.U., Arcenillas, Zamora

		• Establishment name, S.C.A. Ganadera del Valle de los Pedroches (COVAP), Dehesa Boyal
Swine processing establishments	6	• Establishment No. 14, Campofrio Food Group S.A., Torrijos • Establishment No. 30, Pernils Llémena S.A., Sant Aniol de Finestres • Establishment No. 16, Grupo Empresarial Palacios Alimentación S.A., Albelda de Iregua • Establishment No. 24, Industrias Cárnicas El Rasillo S.A., El Rasillo • Establishment No. 44, HPP Food Technology, Madrid • Establishment No. 46, Frigoríficos Costa Brava S.A., Vilamalla

FSIS performed the audit to verify that the food safety inspection systems meet 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.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR part 301 to the end).

The audit standards applied during the review of Spain's inspection systems for raw and processed pork and raw lamb, sheep, and goat products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From January 1, 2021, to December 31, 2023, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 59,767,990 pounds of meat from Spain. This included 1,054,472 pounds of RTE salt-cured pork; 53,309 pounds of RTE pork fully cooked without subsequent exposure to the environment; 7,013 pounds of RTE fully cooked pork; 20,099,518 pounds of RTE dried pork; 1,438,976 pounds of RTE acidified/fermented pork (without cooking); 37,045,147 pounds of raw intact pork; 39,373 pounds of raw non-intact pork; and 30,182 pounds of NRTE otherwise processed pork exported by Spain to the United States. Of these amounts, additional types of inspection were performed on 6,205,239 pounds of meat (110,337 pounds of RTE salt-cured pork; 6,787 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 1,467 pounds of RTE fully-cooked pork; 2,802,067 pounds of RTE dried pork; 214,510 pounds of RTE acidified/fermented pork (without cooking); 3,060,777 pounds of raw intact pork; 6,525 pounds of raw non-intact pork; and 2,769 pounds of NRTE otherwise processed pork). These additional types of inspection included physical examination, chemical residue analysis, and testing for microbiological pathogens (*Listeria*

monocytogenes (*Lm)* and *Salmonella* in RTE products). As a result of the additional physical inspections, 19,681 pounds of meat were rejected for issues related to public health, including off condition and contaminated products. FSIS reviewed MSAN's reports of its investigations regarding these POE violations which included the verification of the establishments' corrective actions, found them sufficient, and closed the POE violations. An additional 65,807 pounds of pork products were refused for other issues not related to public health including shipping damage, labeling, or other miscellaneous issues.

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

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

The first equivalence component 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.

The FSIS auditors verified that the national inspection system is organized and administered by the national government of Spain. As a member of the European Union (EU), Spain has adopted the EU legislation pertaining to food of animal origin and bases its authority to enforce inspection laws on the European Commission (EC) regulations. The EU regulations are the primary overarching laws for regulating meat inspection. Spain is responsible for ensuring that adulterated or misbranded products are not exported to the United States through their national legislation and implementing regulations. In addition to meeting the requirements of the EU, Spain requires establishments exporting to foreign countries to meet the requirements of those countries, which include the Unites States.

The responsibility for Spain's meat inspection control system lies with MSAN and the Ministry of Agriculture, Fisheries and Food (MAPA). MSAN is Spain's CCA responsible for all activities related to the export of meat products to the United States. MSAN is primarily responsible for food safety. MSAN has responsibility for the direct authorization and supervision of the export establishments, developing and implementing controls over the products they produce, and ensuring that, from a public health perspective, establishment operating procedures and production processes are safe. MAPA is principally responsible for animal health, animal identification and traceability, plant health, sanitary agreements with third countries, coordination of sanitary and phytosanitary surveillance, and control at border inspection posts through the Directorate General for Health of Agricultural Production. Animal welfare, animal feed, and primary production of food of animal origin fall under the responsibility of the Directorate General for Agricultural Production and Markets.

Spain's food safety inspection system is organized into central, regional (autonomous community (AC)) and local inspection levels. At the central level, the overall responsibility for

the organization and coordination of control systems is shared between MAPA and MSAN. The regional departments of health carry out the operational implementation of official controls in Spain via 17 ACs, and the two autonomous cities of Ceuta and Melilla have their own Ministries of Agriculture. The AC regional offices are responsible for enforcing regulatory requirements, overseeing in-plant government inspection personnel activities, and providing staffing of government inspection personnel in establishments certified to export to the United States. The veterinary supervisors (VSs) provide direct supervisory authority over the establishments certified to export to the United States in accordance with MSAN requirements. The VSs are also responsible for conducting periodic supervisory reviews at these establishments.

MSAN maintains the legal authority and responsibility to suspend and withdraw export certification of establishments certified as eligible to export to the United States. MSAN inspection procedures authorize MSAN to take enforcement measures such as withdrawal of inspection. MSAN can issue a Notice of Intent to Delist (NOID) or suspend the issuance of export certificates for a product group, a product class, or a process category. A sample of enforcement actions taken by MSAN over the last three years was reviewed during the audit without any concerns. The FSIS auditors verified MSAN has procedures and understands how and when to take enforcement actions.

The FSIS auditors reviewed a sample of noncompliance reports (NRs) generated by in-plant government inspection personnel. The in-plant government inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. In addition, the VSs review these NRs and associated corrective actions on an ongoing basis and during the establishment audits. NRs are documented in a computer application named QUAESTOR. MSAN can review NRs from all establishments and identify trends at individual establishments as well as trends within the entire food safety system. The FSIS auditors review of NRs and associated corrective actions indicated that in-plant government inspection personnel had adequately described noncompliance and verified the effectiveness of the establishment's corrective actions.

The FSIS auditors verified that MSAN has the legal authority and responsibility to certify, suspend, and/or withdraw export approval from establishments certified as eligible to export to the United States. Initial requests for certification are submitted electronically through the Livestock Foreign Trade Export Computer System (CEXGAN) which is an online application. Each establishment applying for certification to export to the United States must follow a specific procedure when applying for certification. MSAN will conduct an initial audit of these establishments with follow-up audits (if needed) to verify corrective actions from the previous audit prior to approving certification. The FSIS auditors reviewed the initial certification of establishment documents from two lamb, sheep, and goat establishments that intend to export products to the United States during the audit without any concerns.

Royal Decree 993/2014 outlines the procedure and requirements of official veterinary certification for the export of animal products. Exporting establishments must be registered, use the CEXGAN online application, and apply for export of meat products. Prior to signing the export certificates, the official veterinarians (OVs) are responsible for ensuring that all requirements for export are met by reviewing documentation, including condition of products

(type, volume, and source), veterinary health certificates, product labeling, HACCP pre-shipment review records, and applicable microbiological and chemical test results to ensure product lots have been reported as satisfactory prior to shipping. This includes ensuring that United States maximum residue limits (MRLs), some of which are more restrictive than the EU's MRLs, are adhered to when evaluating results from chemical residue testing for products intended for export to the United States. The CEXGAN online application is utilized for issuing export certificates. The FSIS auditors interviewed OVs, observed the product certification process, and reviewed export certification records during the audit without any concerns.

The FSIS auditors verified all establishments in Spain are required to develop traceability and recall procedures meeting MSAN requirements. The establishments' procedures are to 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. MSAN has recall procedures in place that include notifying the United States of the recall. MSAN is responsible for contacting FSIS by means of the Embassy of Spain in Washington, D.C., if a shipment of adulterated or misbranded product has been sent to the United States. In addition, the European Union Rapid Alert System for Food and Feed provides an information sharing network that reports foods that pose a risk to human health and requires official action such as withholding, recalling, seizure, or rejection of implicated products.

Annex V of the Ministry Order of April 4, 1995, states that source materials used to produce products for export to the United States must come from establishments certified for export to the United States. Products intended for export to the United States must be produced from source materials that originate from certified establishments in eligible countries, either in Spain or in other EU countries. The OVs must verify the origin of products prior to issuing certification for export to the United States. The FSIS auditors reviewed records and conducted interviews without identifying any concerns with the use of source materials to produce products intended for export to the United States.

MSAN is responsible for auditing these establishments to ensure all EU requirements are met along with requirements specific to the establishments exporting to United States. These establishments are also audited prior to receiving initial certification for export to the United States. In addition to MSAN audits, each AC also conducts audits prior to certification. On an ongoing basis, as determined by risk but at least once per year, the VSs conduct establishment and government inspection personnel audits in these establishments. The ongoing audits are a means to ensure the inspection system is functioning as intended with the establishments meeting requirements and the OVs verifying implementation of food safety systems. The FSIS auditors reviewed audit records and conducted interviews without any concerns.

During the FSIS audit, MSAN demonstrated how recently updated materials were distributed to government inspection personnel at establishments. Each VS conducts establishment and employee audits that verify the standardization of the inspection system and implementation of changes in the inspection system. During the FSIS audit, MSAN provided examples of how updates or guidance information is disseminated throughout the inspection system. When changes are made to the governments food safety inspection system requirements, VSs are required to verify these changes have been implemented at establishments. The FSIS auditors

reviewed and discussed the distribution of information including recent audit results from VSs at establishments without identifying any concerns.

Government inspection personnel covering establishments certified for export to the United States are employees of the regional government ACs. The OVs assigned to the establishments certified for export to the United States are employed and paid directly by the local government. The OVs perform all applicable inspection duties including ante-mortem, post-mortem, sanitation verification, HACCP verification, export verification, and sample collection procedures. AC can utilize official assistants (OA) that are contracted employees employed and paid by a third-party organization (i.e., indirectly paid by the government) conducting limited inspection activities on behalf of the government. All OAs conducting the limited inspection activities are not required to be veterinarians. The limited activities include ante-mortem and post-mortem procedures that are under the direct supervision of an OV. The FSIS auditors interviewed government inspection personnel and reviewed records without concern related to them being paid directly or indirectly by the government.

Staffing of establishments during production of products intended for export to the United States falls under the responsibility of the ACs. During slaughter operations, ACs are responsible for ensuring that adequate (appropriately trained and amount of personnel) government inspection coverage is always present at the slaughter establishments. Processing establishments are required to inform the AC when they intend to produce products for export to the United States. OVs are required to perform inspection activities at least once per production shift during the processing of products intended for export to the United States. The ACs are responsible for providing relief government inspectors due to planned or unplanned absences of government inspection personnel. In the event a relief government inspector is needed, the AC implements the replacement system procedure to ensure that appropriately trained replacements are utilized from the temporary staff pool.

Government inspection personnel working for the government are hired through a public selection process and must have a degree in veterinary medicine. All new veterinarians assigned to establishments that export to the United States must take a public examination and complete training on requirements specific to the United States. After initial training, the new veterinarians must take an online assessment prior to employment. Online training is provided for MSAN personnel on an ongoing basis or whenever changes are made to the inspection system. The FSIS auditors interviewed government inspection personnel and reviewed training records without identifying any concerns with the hiring and training process.

Annex V of the Ministry Order of April 4, 1995, gives the central government the legal authority to approve and disapprove laboratories conducting analytical testing. Laboratories involved in the analysis of products exported to the United States are under the control of MSAN through the General Directorate on Public Health, Quality, and Innovation. The National Accreditation Entity (ENAC) is the accreditation body responsible for verifying overall compliance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. MSAN and ENAC audit laboratories annually. The laboratories also perform internal audits according to their quality assurance manual. The laboratories that analyze official control samples, including reference laboratories, must be designated by the competent

authority responsible for official controls, following the criteria and requirements established in Regulation (EU) 2017/625.

The FSIS auditors reviewed the most recent MSAN and ENAC annual audit reports of the laboratory. These audits documented a few nonconformances, which were addressed and corrected by the laboratory's quality control department. The FSIS auditors reviewed the qualifications of technicians, training records, proficiency testing, and laboratory quality control records. FSIS auditors verified that MSAN does not allow retesting of samples with violative or unacceptable results for products exported to the United States. Additionally, FSIS auditors verified that the laboratory maintains sample integrity and sample traceability throughout the entire process from sample receipt to reporting the of the results. In addition to reviewing documentation, the FSIS auditors interviewed laboratory personnel and reviewed records of analysis. The following finding was identified.

- An official government microbiological laboratory, the Regional Laboratory of the Autonomous Community of La Rioja, was not properly documenting the sample analysis procedure for detection of *Salmonella* and *Lm* in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubator during various phases of analysis.

Apart from the finding, the auditors verified that Spain's pork, lamb, sheep, and goat products inspection systems are organized and administered by the national government, and that MSAN inspection personnel are assigned to enforce the laws and regulations governing these meat products.

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 equivalence component 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 every carcass and its 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.

Spain is required by the EU to meet requirements outlined in Council Regulation (EC) No. 1099/2009, Regulation (EU) 2017/625, and Regulation (EC) No. 853/2004, that outline requirements for the humane treatment of animals at all stages of production including transportation to establishments. The Royal Decree 37/2014 specifies the requirements relating to the protection of animals at the time of slaughter. OVs are trained in humane handling and observe the establishments' implementation of humane handling each day during routine operations. The FSIS auditors reviewed records, directly observed humane handling verification

procedures, and conducted interviews without any concerns regarding MSAN verification activities of animal welfare.

Prior to slaughter, ante-mortem inspection is required to be performed on animals as described in Regulation (EU) 2017/625 which addresses official controls and other activities to ensure application of the requirements. Specific criteria and conditions to perform ante-mortem inspection are outlined in Commission Delegated Regulation (EU) 2019/624 and Commission Implementing Regulation (EU) 2019/627. OVs or OAs are responsible for performing ante-mortem inspection at establishments exporting to the United States which must be conducted within 24 hours of arrival at the establishment and within 24 hours prior to slaughter. Ante-mortem inspection of all animals must be performed by OVs or by inspectors under their supervision before slaughter. The ante-mortem inspection procedures identify if animal welfare has been threatened, any condition which might harm human or animal, the detection of zoonosis, the detection of notifiable diseases, symptoms leading to suspicion of transmissible spongiform encephalopathy (TSE) in small ruminants, and the detection of any sign that could be suspect of the administration of illegal substances. As a preliminary step in ante-mortem inspection, the Royal Decree 361/2009 outlines that food chain information (FCI) must be secured by establishments and reviewed by an OV prior to the slaughter of animals. The FCI is a historical document identifying the origin, history, and animal health status. The FSIS auditors interviewed government inspection personnel, directly observed OVs performing ante-mortem procedures, and reviewed records during the audit and did not identify any concerns with the implementation of ante-mortem inspection procedures.

Post-mortem inspection is required to be performed on animals as described in Regulation (EU) 2017/625 which addresses official controls and other activities to ensure application of the requirements. Specific criteria and conditions to perform post-mortem inspection are outlined in Commission Delegated Regulation (EU) 2019/624 and Regulation (EU) 2017/625. The post-mortem requirements to be performed by government inspection personnel are laid out in the repealed Regulation (EC) No. 854/2004 (Version 01/07/2013). Although Regulation (EU) 2017/625 repealed Regulation (EC) No. 854/2004, veterinarians follow EC-specific requirements in order to be comparable to the FSIS requirements. This requires OVs to use procedures including incision and palpation during post-mortem inspection on carcasses and parts for establishments exporting product to the United States. The OVs are primarily responsible for post-mortem inspection and can be supported by OAs at establishments. MSAN post-mortem inspection procedures for swine, lamb, sheep, and goat are consistent with the post-mortem inspection procedures described in the FSIS Directive 6100.2. The FSIS auditors interviewed government inspection personnel, directly observed post-mortem inspection procedures, and reviewed records without identifying any concerns with post-mortem inspection procedures.

Maximum line speed rate and government staffing standards for online government inspection personnel are supervised by the AC. Establishments are only allowed to run at speeds that maintain food safety, worker safety, animal welfare, and quality. Line speeds are determined by the AC based on the slaughter system and the volume of inspection procedures conducted by government inspection personnel at each establishment. The FSIS auditors interviewed government inspection personnel, directly viewed line speeds, reviewed records, and confirmed

that line speeds and the government staffing standards are consistent with FSIS requirements for livestock slaughter operations.

The performance evaluation of government inspection personnel is outlined in MSAN supervision procedures. Within MSAN is the Sub Directorate General of Foreign Health (SGSE) who performs evaluations on the ACs. The SGSE conducts supervisory visits of the VSs at least once every two years. These visits are designed to assess the performance of an AC which has certified establishments exporting products to the United States and the results are documented in a report provided to the AC after the visit. The VSs conduct performance evaluations of government inspection personnel at least once per year assessing their knowledge, skills, and abilities for implementing procedures. The FSIS auditors interviewed supervisors from the SGSE, VSs, and reviewed supervisory reports without any concerns with MSAN supervisory procedures.

The FSIS auditors verified MSAN requires certified establishments to be separated from non-certified establishments, and the facilities are independent. Annex V of the Ministry Order of April 4, 1995, indicates that raw material must come from United States approved establishments. If an establishment processes product intended and not intended for export to the United States, establishments are required to have a written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and export. Establishments that only produce products eligible for exporting to the United States are not required to have segregation procedures. OVs verify establishments meet the requirements for product tracking, segregation, and origin of raw materials on an ongoing basis.

Labeling requirements for Spain are outlined in Notice 2/95, Special Conditions of Labeling and Packing Materials for Export of Meat and/or Meat Products to the U.S. These requirements are based on FSIS labeling requirements and must be followed by establishments exporting to the United States. Label verification procedures are outlined in MSAN's documents, Inspection Procedures Approved Establishment USA, Revision 10 and Notice 2/95. Whenever products are produced for export to the United States the OVs verify it is properly labeled. At least annually the establishments label approval process is verified. Label verification procedures are also required during AC and MSAN supervisory visits. The FSIS auditors interviewed government inspection personnel, observed implementation of label verification by the OVs, and reviewed records without any concerns with MSAN label verification procedures.

MSAN requires procedures to ensure the raw meat products are derived from the correct species. Currently, only pork products are approved for export to the United States. Species testing is required at establishments that produce ground products such as sausages. Each establishment has four samples analyzed each year at the National Food Center. In addition to species testing, other controls have been established such as product formulation verification and ensuring the proper labeling of raw ingredients prior to processing. Species verification procedures will also apply to establishments exporting raw lamb, sheep, and goat products. The FSIS auditors interviewed personnel and reviewed records without any concerns with the verification of species.

MAPA and MSAN are responsible for ensuring that APHIS requirements are implemented as required. When APHIS restrictions are required, procedures mandate that OVs verify compliance at establishments exporting products to the United States. Additional procedures are usually incorporated into the food chain regarding APHIS requirements. The FSIS auditors did not have any concerns with MAPA or MSAN communication procedures, OVs verification, and identification of APHIS requirements.

Legislation concerning condemned animals and inedible materials are described in Regulations (EC) No. 852/2004, 853/2004, 1069/2009, Regulation (EU) 2017/625, and Commission Regulation (EU) No. 142/2011 which establish health rules regarding animal by-products and products not intended for human consumption. Establishments must maintain control and separation over inedible materials during production. OVs conduct verification activities at establishments to ensure MSAN requirements are implemented. The FSIS auditors interviewed government personnel, directly observed controls, and reviewed records without any concerns with MSAN verification activities regarding the control of condemned and inedible materials.

The FSIS auditors concluded that MSAN maintains the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over establishments producing pork, lamb, sheep, and goat products using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

The requirements for sanitary dressing of livestock throughout the slaughter operations are included in Regulation (EC) No. 853/2004. OVs and OAs verify that establishments have written procedures that are implemented correctly ensuring livestock are slaughtered and processed in a sanitary manner. The FSIS auditors interviewed government inspection personnel, directly observed sanitary dressing verification, and reviewed records without any concerns with MSAN verification ensuring the cleanliness of livestock during slaughter and processing.

MSAN requires establishments to develop, implement, and maintain written procedures in their HACCP plans, Sanitation SOPs, or other pre-requisite programs to prevent contamination of livestock carcasses and parts by enteric pathogens, fecal material, ingesta, and milk. Specifically, establishments must have a critical control point (CCP) for verification of zero tolerance for visible fecal material, ingesta, and milk. Establishments must have a means to trim contaminated carcasses off-line. OVs are required to reinspect each carcass being trimmed by the establishment after the establishment places them back on-line before the on-line government inspection station. The FSIS auditors interviewed government inspection personnel, directly observed MSAN verification activities, and reviewed records without any concerns with verification that carcasses are free of visible contamination.

MSAN has developed inspection verification procedures designed to ensure that each livestock carcass, head, and viscera is free of visible fecal material, ingesta, and milk. OVs perform daily verification procedures that include verification by direct observation of the CCP designed to ensure compliance with zero tolerance in slaughter establishments. The FSIS auditors interviewed government inspection personnel, observed MSAN verification of the zero tolerance CCP, and reviewed records without identifying concerns with MSAN requirements for zero tolerance verification.

Spain is required to follow the requirements set out in Regulations (EC) No. 852/2004 and 853/2004. Regulation (EC) No. 852/2004 outlines the specific requirements for slaughterhouses and cutting plants to prevent insanitary conditions. Regulation (EC) No. 853/2004 specifies the general requirements for all establishments to prevent insanitary conditions. MSAN documents require establishments to comply with requirements consistent with 9 CFR 416 and requires OVs to verify compliance. Establishments are audited by MSAN against the FSIS requirements consistent with 9 CFR 416.1–416.5 prior to being certified as eligible to export products to the United States. These SPS requirements include pest management, construction, control of inedible materials, employee hygiene, sanitation of equipment, ventilation, and sanitary operations. Once certified as eligible to export to the United States, MSAN government inspection personnel routinely verify these requirements following the Inspection Procedures Approved Establishment USA. The FSIS auditors verified through interviews of government inspection personnel, direct observation of establishments, and records review that MSAN requires establishments to meet SPS requirements consistent with 9 CFR 416.1–416.5 and the OVs conduct verification procedures.

MSAN has regulatory requirements for establishments exporting pork products or that intend to export raw lamb, sheep, and goat products to the United States regarding Sanitation SOPs. These establishments must include both pre-operational and operational procedures according to MSAN guidelines SSOP 2019-07. Apart from the EU requirements, Spain has adopted requirements consistent with 9 CFR 416.11–416.17. OVs conduct verifications of the Sanitation SOP requirements according to FSIS Directive 5000.1. These verifications include the evaluation of written sanitation programs, monitoring, and implementation of sanitation procedures, records review, and direct observation verification of both pre-operational and operational procedures.

MSAN can take enforcement actions in case of systemic problems with sanitation requirements. For example, reinforcement measures have been adopted to tackle ventilation issues. The OV enters sanitation verification data into QUAESTOR, which is analyzed by MSAN and the AC to detect trends of noncompliance. When trends of noncompliance related to ventilation are detected, a Sanitation SOP verification task is scheduled daily for government inspection personnel. The measures to tackle ventilation issues require actions involving both the establishments and the OV. The FSIS auditors interviewed government personnel, observed verification of Sanitation SOPs, and reviewed records without identifying any concerns related to MSAN's ability to verify Sanitation SOP requirements.

The FSIS auditors determined that MSAN requires establishments exporting pork products or that intend to export raw lamb, sheep, and goat products to the United States to develop,

implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs, and sanitary dressing.

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

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

EU legislation requires all food establishments to develop, implement, and maintain a HACCP system incorporating the seven principles of HACCP. The EU legislation outlining these requirements are found in Regulations (EC) No. 852/2004, 853/2004, 178/2002 and Regulation (EU) 2017/625. MSAN has adopted the FSIS requirements consistent with 9 CFR 417 for all establishments exporting pork products or that intend to export raw lamb, sheep, and goat products to the United States. MSAN outlines legislation for HACCP requiring establishments to develop, implement, and maintain HACCP programs consistent with 9 CFR 417.

OV inspection procedures are outlined in the Inspection Procedures Approved Establishment USA. These OV inspection procedures outline the evaluation of written HACCP programs and verification of HACCP prerequisites, monitoring, corrective actions, and recordkeeping. MSAN and AC conduct reviews of HACCP program design and implementation on a yearly basis. The OVs verify HACCP requirements once a week for products produced at the establishment that are eligible for export to the United States. Verification activities include initial validation and pre-shipment review requirements. All inspection records regarding official HACCP controls are documented in QUAESTOR. MSAN and AC conduct HACCP program reviews during supervisory reviews. The design and implementation of all establishment's HACCP programs are reviewed at least annually. Additionally, MSAN and AC verify that government inspection personnel HACCP verification activities are providing adequate oversight. The FSIS auditors interviewed government personnel, observed verification of HACCP requirements, and reviewed records without identifying any findings.

The FSIS auditors determined that MSAN requires establishments exporting pork products or that intend to export raw lamb, sheep, and goat products to the United States to develop, implement, and maintain a HACCP system for each processing category consistent with 9 CFR 417.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

MAPA and MSAN develop the National Plan for Official Control of the Food Chain (PNCOCA) in accordance with Regulation (EU) 2017/625 and develop the National Residue Research Plan (PNIR). PNCOCA consists of two specific testing programs: (1) on-farm and (2) in food (Program 15) in accordance with Regulation (EU) 2017/625. PNIR includes both a routine and targeted plan, which includes samples generated for cause. MRLs are set in EU Regulations (Commission Regulation (EU) No. 37/2010 for veterinary drugs, Commission Regulation (EU) 2023/915 for environmental contaminants, and Regulation (EC) No. 396/2005 for pesticides, among others). However, MSAN has implemented a specific procedure to evaluate results of all chemical residue samples collected from livestock when U.S. MRLs are more restrictive than EU MRLs.

The PNCOCA provides the framework program for the official control of contaminants, pesticides, veterinary drug residues, and banned substances. EU member countries are required by the EC to update their national residue control plans annually based on the results of the previous year in order to consider any changes in chemical groups and detection measures and based on the number of slaughtered animals. Spain's PNIR is prepared annually and 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 FSIS auditors confirmed that in addition to meeting EU requirements, chemical residue results are evaluated against United States tolerances when sampled products are intended for export to the United States.

The FSIS auditors verified that in-plant government inspection personnel who collect the residue samples are following MSAN 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 2024 sampling program was being implemented as scheduled.

The FSIS auditors verified Spain requires establishments to hold any livestock products tested for chemical residues pending acceptable results. Each time a violative result is detected, MSAN requires corrective actions and ensuring violative product is kept out of commerce. The procedure includes actions to gather all necessary information to carry out an investigation, identify all implicated product(s) and animals, implement additional sampling and testing, and in some cases to issue monetary sanctions. The FSIS auditors verified in-plant government inspection personnel understand what is required at establishments when carcasses are sampled and if tolerances are exceeded.

The FSIS verification activities indicate that MSAN has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs, pesticides, and environmental contaminants in pork, lamb, sheep, and goat products intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component 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 prepared for export to the United States is safe and wholesome.

Slaughterhouses in Spain must comply with Commission Regulation (EC) No. 2073/2005 and must analyze aerobic plate count, Enterobacteriaceae and *Salmonella* on pig carcasses in order to verify that the slaughter process is under control. Samples are taken before refrigeration and must comply with the limits established in the Commission Regulation (EC) No. 2073/2005. MSAN also requires slaughterhouses exporting products to the United States to meet the requirements in MSAN Circular No. 1/2013 on Hygiene Control of the Slaughtering Process Pathogen Reduction Programs in Slaughterhouses Approved for Exporting Meat to the U.S.A. This procedure includes requirements for sampling of Enterobacteriaceae pre- and post-evisceration. Spain permits the post-evisceration sample to be collected either prior to or after the chilling step. OVs verify that establishments are conducting indicator organism sampling by direct observation and records review. MSAN audits the program at least once per year during establishment supervisory visits. When a noncompliance is observed with the establishment's indicator organism testing program, MSAN issues an NR. If multiple recurring noncompliances are observed, MSAN can issue a Notice of Intent to Delist or the establishment approval to operate can be withdrawn. The FSIS auditors interviewed government inspection personnel, observed government inspection verification activities, and reviewed records without identifying any findings with the verification and implementation of establishment indicator organism testing requirements.

MSAN has updated Circular No. 1/2013 (Revision 2024) to include requirements for establishment sampling of lamb, sheep, and goat carcasses for Enterobacteriaceae, aerobic plate count, and *Salmonella* to monitor for process control during slaughter in accordance with Commission Regulation (EC) No. 2073/2005. The FSIS auditors verified the lamb, sheep, and goat establishments intending to export products to the United States are meeting MSAN indicator organism sampling requirements.

MSAN has adopted a zero-tolerance approach for *Lm* and *Salmonella* in RTE products that is consistent with FSIS policy. OVs conduct sampling for verification of the establishments' food safety controls and establishments are to have a sampling program in place that is consistent with 9 CFR 430. Testing by MSAN and establishments for *Lm* is required for products, food contact surfaces of post lethality production lines, and the environment of establishments and is described in MSAN's Official Microbiological Verification Program in Production Lines of Ready-to-Eat Foods (RTE) (Sampling in Product, FCS, and NFC). Official testing frequencies are established based on the alternative used by the establishments. *Salmonella* testing is required for RTE products at the same frequency as *Lm* product testing. In the event of a positive result of *Salmonella* in product, sampling of the product and the post-lethality environment, including both food contact and environmental surface sampling, is compulsory.

RTE product is considered adulterated if it contains *Lm* or *Salmonella*, or if it comes into direct contact with a food contact surface that is contaminated with *Lm* or *Salmonella*. In the event of positive results for *Lm* or *Salmonella* in product, these products would not be eligible for export

to the United States. MSAN has developed procedures for the OVs to follow regarding any positive test results in RTE production lines. All positive results can be viewed on QUAESTOR and MSAN is involved in actions and verification of corrective actions for each case. MSAN closely supervises the cases through communication with the VSs and SGSE supervisors. The FSIS auditors interviewed government inspection personnel, observed sampling procedures, and reviewed records without identifying concerns with *Lm* and *Salmonella* sampling and testing requirements.

MSAN requires establishments producing RTE products that do not rely on cooking to achieve lethality to have in place parameters such as water activity and acid levels that provide for the control of pathogenic microorganisms. These parameters must be included in procedures outlined in the establishments' prerequisite programs or be linked to a CCP in the HACCP system. The establishment must maintain supporting documents for the decisions regarding these parameters. Establishments exporting to the United States must follow EU and MSAN requirements regarding these parameters as well FSIS requirements. The FSIS auditors interviewed government inspection personnel, directly observed government inspection personnel verification, and reviewed records without concern regarding MSAN verification activities for the production of RTE products without the application of cooking.

MSAN has procedures outlining the verification activities regarding establishment compliance with requirements consistent with 9 CFR 430. These procedures include an evaluation of *Lm* alternative selection by the establishments, Sanitation SOPs, and HACCP procedures at least annually. These procedures include direct observation of the establishment's controls for *Lm* and *Salmonella* and ensure the verification of results in a timely manner and prior to issuing an export certificate for products exported to the United States.

The FSIS auditors determined that MSAN maintains the legal authority to implement its microbiological sampling and testing programs to ensure that pork, lamb, sheep, and goat products intended for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held July 31, 2024, with MSAN. At this meeting, the FSIS auditors presented the preliminary finding 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 finding:

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

- An official government microbiological laboratory, The Regional Laboratory of the Autonomous Community of La Rioja, was not properly documenting the sample analysis procedure for detection of *Salmonella* and *Lm* in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubator during various phases of analysis.

During the audit exit meeting, MSAN committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of MSAN'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
Campofrio Food Group S.A. Torrijos (Toledo)	07/23/2024	14	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	Deboning, Forming, and Slicing of RTE Dried Pork Products

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/23/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Grupo Empresarial Palacios Alimentacion, S.A. Albelda de Iregua, La Rioja	07/15/2024	16	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	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	
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.	

Establishment Operations:	Pork processing.
Prepared Products:	RTE pork products

60. Observation of the Establishment

The following non-compliance was not identified by Spain's inspection officials during the establishment review:

15. The establishment did not identify trichina (a parasitic roundworm) and milk solids (an added ingredient and allergen) as potential hazards within its written hazard analysis for the production of RTE pork products. Further conversations with industry representatives and inspection personnel indicated that there were prerequisite programs in place to address these hazards and render them not reasonably likely to occur. This included the national trichina surveillance program and the establishment allergen control and labeling program. However, failure to identify all potential hazards within the hazard analysis does not meet basic HACCP requirements.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/15/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Industrias Carnicas El Rasillo S.A. El Rasillo de Cameros, La Rioja	07/16/2024	24	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
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.	

Establishment Operations:	Pork processing.
Prepared Products:	RTE Dry-Cured Hams

60. Observation of the Establishment

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

12. Preventive measures were not included as a part of documented corrective actions for operational SSOP deficiencies.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/16/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pernils Llemena S.A CT Girona A Les Planes, KM 23 Sant Aniol De Finestres Girona	07/22/2024	30	Spain
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT X ON-SITE AUDIT ☐ DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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	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.	

Establishment Operations:	Pork processing.
Prepared Products:	RTE and NRTE pork

60. Observation of the Establishment

45,46- After the wash step for whole hams, the belt (food contact surface) had accumulation of a foreign matter in spots on the edge. No product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/22/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorificos Costa Brava . Ct de Riudellots a Cassa S/N Riudellots de la Selva (Girona)	07/18/2024	33	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	RTE and NRTE pork

60. Observation of the Establishment

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/18/2024

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. CTRA Vic-Olot Km. 11, 08511 Santa Maria Corco (Barcelona)	07/23/2024	37	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw, RTE and NRTE pork

60. Observation of the Establishment

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/23/2024

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 . C/Galileo Galilei n ll, Naves 2 y 3 Getafe (Madrid)	07/22/2024	44	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	High-pressure processing of pork.
Prepared Products:	RTE and NRTE pork

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/22/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorificos Costa Brava SA CR de Rosas s/n Villamalla (Girona)	07/19/2024	46	Spain
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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.	

Establishment Operations:	Pork processing.
Prepared Products:	Raw pork

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/19/2024

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
Jamones Y Embutidos Jaem, S.A. Calle Pozo, 2 - Bj Villar De Gallimazo, 37320 Salamanca	07/10/2024	48	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw-intact pork.

60. Observation of the Establishment

The following non-compliance was not identified by Spain's inspection officials during the establishment review:

18. The establishment employee responsible for monitoring the “zero tolerance” critical control point (CCP) for feces, ingesta, and milk was not observing the entirety of the carcass during monitoring procedures (with portions of the head omitted).

In addition, FSIS identified the following findings related to the implementation of Spain's inspection system:

55. Post-mortem inspection: A) The lighting at the point of head inspection was insufficient. The lighting intensity at this point was 270 Lux, rather than the 540 Lux required by Spain’s inspection requirements; and B) The government viscera inspector was not properly palpating the mesenteric lymph node chain during post-mortem (swine) inspection activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/10/2024

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
Carnicas Cinco Villas, S.A.U.	07/15/2024	49	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Slaughter and pork processing.
Prepared Products:	Raw pork

60. Observation of the Establishment

25-A combo bin of pork ribs was observed in the packing area without a label.

51,55-When performing post mortem inspection: inspection personnel were not following MSAN requirements outlined in the OFFICIAL MICROBILOGICAL VERIFICATION PROGRAM IN SLAUGHTERHOUSES Rev.5 (05/09/2024), Annex II.

22-Calibration verification records did not include the time the event occurred for CCP2.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/15/2024

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
Moralejo Seleccion, SLU. Arcenillas/Zamora Castilla y Leon	07/11/2024	Pending Assignment.	Spain
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Lamb slaughter and processing.
Prepared Products:	Raw processing

60. Observation of the Establishment

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

22. The establishment did not routinely document the time of entry for the element of “review of records” within their HACCP verification procedures.

57. The blades of the leg-cutter used for on-hide lamb carcasses were not sanitized between each animal.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/11/2024

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
S.C.A Ganadera del Valle de los Pedroches (COVAP) Cordoba (Andalucía)	07/23/2024	Pending Assignment	Spain
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Sheep and goat slaughter.
Prepared Products:	Raw processing

60. Observation of the Establishment

39 In the chilling cooler for US lamb production multiple support beams were dirty on the bottom. These areas appeared to have rusting and dirt accumulating on the bottom of the structures near the floor.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/23/2024

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

MINISTERIO
DE AGRICULTURA, PESCA
Y ALIMENTACIÓN

Valentín Almansa de Lara
DIRECTOR GENERAL DE SANIDAD DE LA PRODUCCIÓN AGROALIMENTARIA Y BIENESTAR ANIMAL

Dra. Margaret Burns Rath

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

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

Madrid, 12 December 2024

Dear Dra. Margaret Burns Rath,

It is a pleasure to greet you from the General Directorate of Agrifood Production Health and Animal Welfare of the Ministry of Agriculture, Fisheries and Food.

As you have already been informed, pursuant to Order PJC/756/2024, of July 22, delimiting the actions to be carried out in the official border control services, the Ministry of Health's export competencies are delegated to the Ministry of Agriculture, Fisheries and Food.

For this reason, it is currently this Ministry, through the Subdirectorate General for Sanitary Agreements and Border Control, which assumes all aspects related to guaranteeing compliance with U.S. regulations by establishments authorized to export meat and meat products and by the Official Veterinary Services in charge of official control and assumes the role of Central Competent Authority (CCA).

Having assumed this role on our part, and in reply to your letter dated 17 October 2024 and the draft report of the audit carried out by FSIS between 8 and 31 July, please find attached a letter with:

(1) Clarification to the FSIS report

(2) System actions to the non-conformity detailed in the FSIS report

(3) Actions taken at the establishments in response to the specific findings observed in the audit

(4) Assignment of US approved establishment number for sheep and goat establishments

I take this opportunity to show you my most distinguished consideration and I hope that we can collaborate in a close way.

CORREO ELECTRÓNICO:

exportacionanimal@mapa.es

C/ ALMAGRO, 33, 3º planta
28010 - MADRID
TEL: +34 913478243
FAX: +34 913476969

MINISTERIO
DE SANIDAD

DIRECCION GENERAL DE
SALUD PÚBLICA Y
EQUIDAD EN SALUD

SUBDIRECCIÓN GENERAL
DE SANIDAD EXTERIOR

Dra. Margaret Burns Rath

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

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

Madrid, 11 December 2024

In response to your letter dated 17 October 2024 and the draft report of the audit carried out by FSIS between 8 and 31 July. Please find attached a letter with:

(1) Clarifications to the FSIS report.
(2) System actions to the non-conformity detailed in the FSIS report.
(3) Actions taken at the establishments in response to the specific findings observed in the audit.
(4) Assignment of US approved establishment number for sheep and goat establishments.

Yours sincerely,

EL SUBDIRECTOR GENERAL,
Fernando Riesco Rodríguez

(1) CLARIFICATIONS TO THE FSIS REPORT.

The following aspects of the FSIS draft report received on 17 October 2024 are hereby forwarded to be taken into account in the drafting of the final report:

- On page 1, section **AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**, it is mentioned "*at the time of the onsite audit Spain did not have any establishments certified to export to the United States producing Fully Cooked-Not Shelf Stable pork products"*. However, at the time of the audit, establishment nº 16 - GRUPO EMPRESARIAL PALACIOS ALIMENTACION, S.A., which produces products of this category that are used as raw material in the pizzas they produce, had already been included.

- In the first paragraph of page 3 of the **AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY** section, it is stated that the audit included 5 pork processing establishments. However, there were 6 establishments, as indicated in the table on page 4.

- In the section of the table 'Swine processing establishments' on page 4 of the **AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY** section, establishment Nº 22 (CAMPOFRIO FOOD GROUP S.A., Burgos) is mentioned. However, the establishment that was audited was **Nº 14 (CAMPOFRIO FOOD GROUP S.A., Torrijos)**.

- In the first paragraph of page 7, **COMPONENT ONE: GOVERNMENT OVERSIGHT**, it is stated 'The QUAESTOR online application is used for issuing export certificates'. However, the issuing of export certificates is carried out through CEXGAN. QUAESTOR is used for issuing transit certificates between approved establishments and for recording the controls carried out by the inspectors of the US establishments. QUAESTOR also documents the verification of pre-shipment checks prior to the issuance of export certificates to the USA that are issued by CEXGAN.

- On page 8, second paragraph, **COMPONENT ONE: GOVERNMENT OVERSIGHT**, it states 'All OAs conducting the limited inspection activities are veterinarians'. However, Official Assistants may or may not be veterinarians (it is not a prerequisite to be a veterinarian).

- In **APPENDIX A**, specifically in the report of the establishment Nº 30 - Pernils Llemena S.A, in section 60: Observation of the establishment, in the final report issued by FSIS, item 44 was erroneously moved instead of item 45.

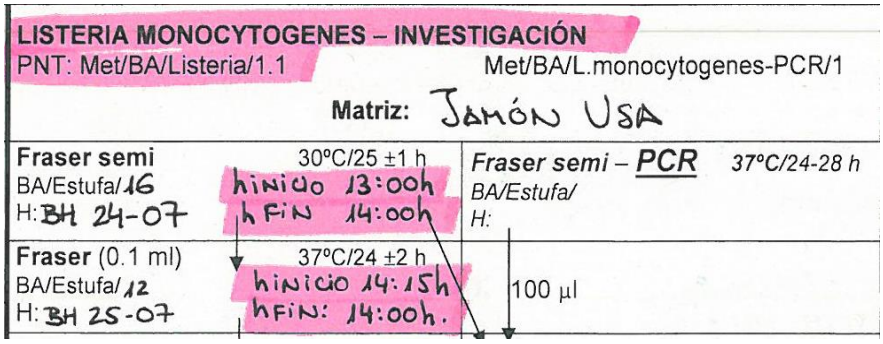
- In **APPENDIX A**, specifically in the report of the establishment S.C.A Ganadera del Valle de los Pedroches (COVAP), In section 1: Establishment name and location, in the final report issued by FSIS, the location was incorrect ("Córdoba" instead of "Doba").

(2) SYSTEM ACTIONS.

System non-conformity - COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

An official government microbiological laboratory, the Regional Laboratory of the Autonomous Community of La Rioja, was not properly documenting the sample analysis procedure for detection of *Salmonella* and *Listeria monocytogenes* in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubator during various phases of analysis.

In relation to the Regional Laboratory of the Government of La Rioja, it has modified its records. These include the start and end times of the incubation period, as can be seen below in a clipping from the register:



LISTERIA MONOCYTOGENES – INVESTIGACIÓN

PNT: Met/BA/Listeria/1.1 Met/BA/L.monocytogenes-PCR/1

Matriz: JAMÓN USA

Fraser semi BA/Estufa/16 H: BH 24-07	30ºC/25 ±1 h hINICIO 13:00h hFIN 14:00h	*Fraser semi – PCR* 37ºC/24-28 h *BA/Estufa/* *H:*
Fraser (0.1 ml) BA/Estufa/12 H: BH 25-07	37ºC/24 ±2 h hINICIO 14:15h hFIN: 14:00h.	100 µl

Likewise, this aspect has been discussed with the 6 official laboratories (11/27/2024) that take part in the US program and all of them record the incubation times, which makes it possible to demonstrate compliance with the times required in the methods.

Finally, compliance with the registration of incubation times will be one of the aspects verified in the supervision actions carried out annually by the central authority in the laboratories.

(3) ACTIONS TAKEN AT THE ESTABLISHMENTS IN RESPONSE TO THE SPECIFIC FINDINGS OBSERVED IN THE AUDIT.

The actions taken at the establishments in response to the specific findings observed in the audit are collected in the tables below.

With the exception of non-conformity 51 and 55 of Establishment Nº 49, the content set out in the “corrective actions” column has been extracted from the application QUAESTOR of Ministry of Health.

In QUAESTOR, the Official Inspectors recorded non-conformities, the establishments responded to them by providing evidence of correction, and inspectors carried out appropriate follow-ups until the non-conformities were closed.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Grupo Empresarial Palacios Alimentación, S.A. Albelda de Iregua, La Rioja	**16**	**15.** Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	**15**: The establishment did not identify trichina (a parasitic roundworm) and milk solids (an added ingredient and allergen) as potential hazards within its written hazard analysis for the production of RTE pork products. Further conversations with industry representatives and inspection personnel indicated that there were prerequisite programs in place to address these hazards and render them not reasonably likely to occur. This included the national trichina surveillance program and the establishment allergen control and labeling program. However, failure to identify all potential hazards within the hazard analysis does not meet basic HACCP requirements.	The establishment has included *Trichinella spiralis* (biological hazard) and milk protein allergen (chemical hazard) as potential hazards in the hazard identification document. The risk characterization has taken into account, in the case of *Trichinella*, the low likelihood of occurrence and the existence of a national surveillance program whereby all slaughtered pigs are tested for trichina prior to shipment. In the case of milk protein, the risk characterization has considered the allergen control programme, the control of ingredients and their indication on the labelling; this hazard has been considered low likelihood of occurrence too. The risk analysis has determined the consideration of these hazards as non-significant. For this reason, the establishment has considered that it is not necessary to change the decision-making process. The new version of HACCP and the supporting documents have been reviewed by Official Veterinary Service, leaving a record of its review in QUAESTOR and verifying that the two hazards have been considered by the establishment and have been considered in their risk analysis.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Industrias Cárnicas El Rasillo S.A. El Rasillo de Cameros, La Rioja	**24**	**12**.Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	12. Preventive measures were not included as a part of documented corrective actions for operational SSOP deficiencies.	The establishment has verified that in the pre-operational and operational hygiene deficiencies record, the following sections are detailed to be filled in: description of the deficiency, causes, corrective actions and preventive actions. It is verified that for deficiency 7274 dated 12/01/2023, all sections are completed except the one referring to preventive actions. After interviewing both departments (sanitation and maintenance), a lack of understanding was found with regard to the management of the hygiene deficiency. As it was a mechanical breakdown, the section referring to preventive measures to avoid recurrence was not completed, as these are activities of the maintenance department. Both departments are informed of the operation when a deficiency occurs that involves both departments. To this end, an e-mail is sent to the heads of both departments with acknowledgement and reply. In these cases (mechanical breakdown), the hygiene department will delegate corrective and preventive activities to the maintenance department, the latter not only being responsible for the actions to be carried out, but also for informing the person responsible for hygiene in order to complete and close the hygiene deficiency report correctly. It is verified at later dates and for the equipment referred to that the maintenance activities are not only corrective (fixing the breakdown), but also preventive to avoid recurrence of the mechanical failure have been established by the maintenance department. Finally, the Official Veterinary Service has reviewed that the records include the three parts of the corrective actions.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Pernils Llemena S.A CT Girona A Les Planes, KM 23 Sant Aniol De Finestres Girona	**30**	45. Equipment and Utensils 46. Sanitary Operations	44, 46. After the wash step for whole hams, the belt (food contact surface) had accumulation of a foreign matter in spots on the edge. No product contamination was observed.	As a regulatory measure, the official veterinary service blocks the tape, putting a retention label (no. E-9993). The belt is emptied and stopped to take immediate corrective measures. Line operators clean and disinfect the tape. Once official control has determined that the sanitary condition of the surface has been restored, the tape is unlocked, removing the retention label. The production begins again. Due to the arrangement of the product on hangers, the product must be retained through traceability. To do this, the specific production of the product that could have been produced must be identified, from the beginning of the day to the moment of resolution of the incident. After 6 months, the affected gender will be observed to verify that this incident has not affected the product. Operational controls will be carried out by quality personnel with the aim of improving controls. The visual inspection allows the Official Veterinary Services to verify that there is no repetition of the incident that caused the incident. After various verifications, the Official Veterinary Services proceed to close the incident for not having recurrences of the incidence.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Jamones Y Embutidos Jaem, S.A. Calle Pozo, 2 - Bj Villar De Gallimazo, 37320 Salamanca	**48**	**18.** Monitoring of HACCP plan.	18: The establishment employee responsible for monitoring the "zero tolerance" critical control point (CCP) for feces, ingesta, and milk was not observing the entirety of the carcass during monitoring procedures (with portions of the head omitted).	The employee responsible for monitoring of the CCP was verbally reminded to inspect the head and the inside of the head. The employee responsible for monitoring of the CCP has been instructed through a specific course on correct monitoring. The monitoring procedure of the CCP is subject to daily official verification procedure (03J01) and no problems have been detected from the audit. The Official Veterinary Service has not documented any other non-compliance.
		55. Postmortem Inspection	55. Post-mortem inspection: A) The lighting at the point of head inspection was insufficient. The lighting intensity at this point was 270 Lux, rather than the 540 Lux required by Spain's inspection requirements; and B) The government viscera inspector was not properly palpating the mesenteric lymph node chain during post-mortem (swine) inspection activities.	At the carcass inspection station, an extra light has been provided so that the illumination in the area of the submaxillary ganglions is higher than 540 lux. Measurement is made and a value of 749 lux is obtained at that point. The procedure has been modified to indicate that the light measurement point at the carcass inspection station should be at the most unfavorable point, i.e. inside the head. The Official Veterinary Service has verified the actions taken and closed the Deficiency Record associated with this deviation.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Cárnicas Cinco Villas, S.A.U.	**49**	**25.** General Labeling	25. A combo bin of pork ribs was observed in the packing area without a label.	Block the container without a label with a red locked sticker until the corresponding label is attached and then unblock it. Corrective training for the packaging personnel involved, reminding them of the importance and obligation of all pallets/containers being identified in order to maintain traceability at all times. If the product is transferred from a pallet of E2 boxes to a container (as had been done at the time of the incident) for subsequent dumping on the packaging line, the corresponding label must be immediately placed on the container. The Official Veterinary Service has carried out follow-ups in which it has verified the non-repetition of this incident.
		51. Periodic Supervisory Reviews **55.** Postmortem Inspection	51.55. When performing postmortem inspection: inspection personnel were not following MSAN requirements outlined in the OFFICIAL MICROBILOGICAL VERIFICATION PROGRAM IN SLAUGHTERHOUSES Rev.5 (09/05/2024), Annex II.	After the withdrawal of the seal and the adoption of an Official Control Recommendation to the inspection team on the day of the audit (07/16/2024): urgent meetings were held between the Autonomous Community and the Ministry of Health. The Autonomous Community took urgent measures to ensure postmortem inspection in accordance with established criteria. The proper implementation of the postmortem inspection was verified by Authorities of the Ministry of Health on 07/24/2024. On 07/25/2024, it was reported that the US seal could be re-imposed after verifying that the postmortem inspection was carried out properly. Subsequently, within the framework of an evaluation of the performance of the inspection team, which was accompanied by Authorities of Ministry of Health (09/17/24), it was verified that the measures adopted were maintained. The postmortem inspection was carried out appropriately and the Official Control Recommendation was closed. It has also been strengthened and some points have been clarified of the OFFICIAL MICROBILOGICAL VERIFICATION PROGRAM IN SLAUGHTERHOUSES document and PERIODIC SUPERVISION PROCEDURE IN AUTHORIZED ESTABLISHMENTS IN THE USA document.

		22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	22. Calibration verification records did not include the time the event occurred for CCP2.	The establishment carried out the modification of the CCP metal detectors verification record, including the time at which the control is done. Corrective training for the quality personnel involved in the incident, reminding them of the importance of proper documentation management in order to always use the latest revision in force of each record. The Official Veterinary Service has verified the actions taken and closed the Deficiency Record associated with this deviation.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
Moralejo Seleccion, SLU Arcenillas/Zamora Castilla y Leon	**Pending Assignment.** **According to Resolution 12/10/2024** **Establishment Nº 51**	**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.	We understand that the deviation refers to the verification records of the CCPs for fecal contamination and/or the metal detector where the actual observed value and time were not indicated because this establishment doesn't have pH meter. This non-compliance was transferred in the authorization audit carried out by the General Subdirectorate of Foreign Health of the Ministry of Health on June 4 and 5, 2024, being documented in the deficiencies register 20244363MCC in QUAESTOR. The establishment reviewed the records, recording the justification for the deletions and reflecting the hours correctly. The Official Veterinary Service has verified the actions taken and closed the Deficiency Record associated with this deviation.
		57. Sanitary Slaughter Activities	57. The blades of the leg-cutter used for on-hide lamb carcasses were not sanitized between each animal.	The establishment has included SSOP a sanitation frequency of blades of the leg-cutter to each carcass. In addition, training has been given to the operators. The Official Veterinary Service has verified the actions taken and closed the Deficiency Record associated with this deviation.

ESTABLISHMENT NAME	ESTABLISHMENT NUMBER	AUDIT CHECK LIST	OBSERVATION OF THE ESTABLISHMENT	CORRECTIVE ACTIONS
S.C.A Ganadera del Valle de los Pedroches (COVAP) Pozoblanco, Córdoba (Andalucía)	**Pending Assignment.** **According to Resolution 12/10/2024 Establishment Nº 52**	**39.**Establishment Construction/Maintenance	39. In the chilling cooler for US lamb production multiple support beams were dirty on the bottom. These areas appeared to have rusting and dirt accumulating on the bottom of the structures near the floor.	The cleaning company was notified by the establishment to clean and disinfect the chilling cooler after it was emptied. The establishment verified if there had been affected product. In case of affected product, the affected area was expunged. The carcasses were stored in the central lanes to avoid rubbing against the columns. The Official Veterinary Service has verified the actions taken and closed the Deficiency Record associated with this deviation.