USDA

United States Department of Agriculture

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Food Safety and
Inspection Service

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

Dear Dr. Carreras Vaquer,

The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Spain's meat inspection system from June 1 through 17, 2022. 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,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

SPAIN

JUNE 1-17, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 15, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Spain conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from June 1 to June 17, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether Spain's food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Spain currently exports the following categories of pork products to the United States: raw-intact, raw non-intact, not heat treated-shelf stable, and fully cooked-not shelf stable.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors concluded that Spain's pork inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Ministry of Health (MSAN), as the Central Competent Authority (CCA), has required that establishments certified as eligible to export pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, MSAN has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Spain's food safety system from June 1 to June 17, 2022. The audit began with an entrance meeting held via videoconference on June 1, with the Central Competent Authority (CCA)-Ministry of Health (MSAN). Representatives from MSAN participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether Spain's food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Spain is eligible to export 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
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Not Ready-To-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-To-Eat (RTE) Acidified/Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible
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

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Spain as subject to the following restrictions: African swine fever requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8; classical swine fever requirements specified in

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

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 remote equivalence verification audit, FSIS reviewed and analyzed Spain's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Spain's food safety inspection system governing pork products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from 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 records related to administrative functions and oversight at MSAN headquarters, as well as government verification records from two regional offices, and three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to five meetings each week over a three-week period. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of three establishments was selected for the remote audit from a total of 27 establishments certified to export to the United States. This included two swine slaughter and one swine slaughter and processing establishment. The categories of pork products these establishments produce and export to the United States include raw intact; raw ground, comminuted, or otherwise non-intact pork; NRTE otherwise processed meat; RTE acidified/fermented meat (without cooking); RTE salt-cured meat; and RTE dried meat.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. The FSIS auditors assessed MSAN's ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also remotely audited one government-operated laboratory that conducts chemical residue and microbiological analyses to verify that the laboratory system is capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• Ministry of Health, Madrid
	Regional Offices	2	• Catalonia Regional Department of Health • Castilla y León Regional Department of Health
Laboratory		1	• Valencia Public Health Laboratory, government microbiological and chemical residue, Valencia
Swine slaughter establishments		2	• Establishment No. 33, Frigoríficos Costa Brava S.A., Santa Maria de Corcó • Establishment No. 37, Patel S.A.U., Riuddellots de la Selva
Swine slaughter and processing establishment		1	• Establishment No. 23, Embutidos Fermín S.L., Tamames

FSIS performed the audit to verify that Spain's food safety inspection system meets 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 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Spain's inspection system for pork 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 April 1, 2019, to March 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 44,673,090 pounds of pork from Spain. This included 360,700 pounds of RTE salt-cured pork; 12,082 pounds of RTE pork fully cooked without subsequent exposure to the environment; 24,353 pounds of RTE fully cooked pork; 16,857,145 pounds of RTE dried pork; 1,147,152 pounds of RTE acidified/fermented pork (without cooking); 26,186,530 pounds of raw intact pork; 63,045 pounds of raw non-intact pork; and 22,083 pounds of NRTE otherwise processed pork exported by Spain to the United States. Of these amounts, additional types of inspection were performed on 5,404,905 pounds of pork, including physical examination, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of this additional testing, 23,849 pounds of pork were rejected for issues related to public health,

including off condition product, mold, and *Lm*. FSIS evaluated MSAN's corrective action responses, found them sufficient, and closed the POE violations.

The previous FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Spain
Component 1: Government Oversight (e.g., Organization and Administration)
• The Central Competent Authority (CCA) inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
• The CCA does not require once per shift inspection coverage at High Pressure Processing (HPP) establishments, during pork processing operations, of product destined for export to the United States. • The CCA does not require inspection personnel to perform hands-on inspection verification of the pre-operational sanitation procedures at HPP establishments.
Component 5: Government Chemical Residue Testing Programs
• The CCA's national chemical residue plan has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

The FSIS auditors verified through interviews and review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent FSIS final 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. The 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.

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 pork products to the United States, replacing the Ministry of Health, Consumer Affairs and Social Welfare. 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, control at border inspection posts, animal welfare, animal feed, and primary production of food of animal origin.

Spain's food safety inspection system is organized into central, autonomous communities (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 findings. 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. Noncompliance reports 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 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 records from the last establishment certified for export to the United States were reviewed 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 pork 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 (MRL), 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 QUAESTOR online application is utilized for issuing export certificates. The FSIS auditors reviewed export certification records during the audit and did not identify any findings.

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. The FSIS auditors verified through review of records and interviews that government inspection personnel verify establishments have developed and implemented traceability and recall procedures in accordance with MSAN requirements without any findings.

The FSIS auditors verified 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 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 raw materials 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 originate from certified establishments in eligible countries, either in Spain or in other EU countries. Spain does not utilize raw source materials from countries not belonging to the EU. 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 findings with the use of raw materials from establishments certified 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 inspector 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 government veterinarians verifying implementation of food safety systems. The FSIS auditors reviewed audit records and conducted interviews without any finding.

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 food safety system, 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 findings.

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 government. The OVs are eligible to perform all applicable inspection duties including ante-mortem, post-mortem, sanitation verification, HACCP verification, export verification, and sample collection procedures. One AC utilizes official assistants (OA) that are contracted employees employed and paid by a third party (indirectly paid by the government) conducting limited inspection activities on behalf of the government. All OAs conducting the limited inspection activities are 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 any findings related to them being paid by the government.

Staffing of establishments during production of products intended for export to the United States falls under the responsibility of the AC. During slaughter operations, ACs are responsible for ensuring that adequate (appropriately trained and amount of personnel) government inspection coverage is always maintained. 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. The ACs are responsible for providing relief 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.

In the Ministry Order of April 4, 1995, Annex V 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 national 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 participate in official controls, including reference laboratories, must be designated by the competent authority responsible for official control, 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 have reported a few non-conformances, 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. During the FSIS audit, MSAN demonstrated that retesting of a sample is not allowed for products exported to the United States. Additionally, MSAN demonstrated how sample integrity is maintained and demonstrated sample traceability throughout the entire process from taking the sample to reporting the analysis. In addition to reviewing documentation, the FSIS auditors also interviewed laboratory personnel and did not identify any findings with the government laboratories conducting analysis for products exported to the United States.

The auditors verified that Spain's pork inspection system is organized and administered by the national government, and that MSAN inspection officials are assigned to enforce the laws and regulations governing pork 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 and conducted interviews without any findings 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 the veterinarians 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. In the AC of Catalonia, OVs are supported by OAs. 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 and reviewed records during the audit and did not identify any findings 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 Regulations (EU) 2019/624 and 2017/627. 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 or OAs to use procedures including incision and palpation during post-mortem inspection for establishments exporting product to the United States. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with post-mortem inspection procedures.

There is no specific legal requirement that regulates the number of inspectors according to the slaughter line speed. Maximum line speed rate and government staffing standards for online government inspection personnel is 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 ACs based on the slaughter system and the volume of inspection procedures conducted by MSAN government personnel at each establishment. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with line speeds or the number of government inspection personnel.

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. SGSE conduct 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 and VSs and reviewed supervisory reports without any findings with MSAN supervisory procedures.

The FSIS auditors verified MSAN requires establishments to have written procedures including tracking and segregation. 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 U.S.A. 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. The document also outlines government inspection verification activities regarding labeling. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with MSAN label verification procedures.

MSAN requires procedures to ensure the raw meat products are derived from the correct species. The only meat products establishments export to the United States are pork. 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. The FSIS auditors interviewed personnel and reviewed records without identifying any findings with the verification of species.

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

Legislation concerning condemned animals and inedible materials is 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 and reviewed records without identifying any findings with MSAN verification activities regarding the control of condemned materials.

The FSIS auditors concluded that MSAN continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over pork establishments certified to export their products to the United States 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 FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The requirements for sanitary dressing (slaughter hygiene) of livestock throughout the slaughter operations are included in Regulation (EC) No. 853/2004. OVs and OAs verify that these establishments have written procedures that are implemented correctly ensuring livestock are slaughtered and processed in a sanitary manner. Through interviews and records review, the FSIS auditors verified that MSAN veterinarians verify establishment requirements ensuring the cleanliness of livestock during slaughter and processing.

MSAN requires establishments certified for export to the United States 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 matter, ingesta, and milk. Specifically, establishments must have a Critical Control Point (CCP) for verification of zero tolerance for fecal matter, 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.

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 direct observation verification of the CCP designed to ensure compliance with zero tolerance in slaughter establishments. The FSIS auditors conducted interviews and reviewed records without identifying findings 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 food business operators 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 U.S. Establishments Inspection Procedure, Revision 9. The FSIS auditors verified through interviews 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 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 during the last two years 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 and reviewed records without identifying findings related to MSAN's ability to verify sanitation SOP requirements.

The FSIS auditors determined that MSAN requires establishments exporting to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS, sanitation SOPs, zero tolerance, 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, 78/2002 and Regulation (EU) 2017/625. MSAN has adopted the FSIS requirements consistent with 9 CFR 417 for all establishments exporting products to the United States. MSAN outlines required legislation for HACCP requiring establishments exporting to the United States to develop, implement, and maintain HACCP programs consistent with 9 CFR 417.

OV inspection procedures are outlined in the Inspection Procedures for U.S. Approved Establishments. The OV inspection procedure outlines the evaluation of written HACCP programs and verification of HACCP prerequisites, monitoring, corrective actions, and recordkeeping. MSAN and ACs conduct reviews of HACCP program design and implementation on a yearly basis. The OV inspectors 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 OV HACCP controls are documented in QUAESTOR. The FSIS auditors interviewed government personnel and reviewed records without identifying any findings.

The FSIS auditors determined that MSAN requires establishments exporting 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 pork inspection authorities or by FSIS as potential contaminants.

Prior to the remote audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed Spain's national chemical residue control plan (National Residue Research Plan (PNIR)), the National Plan for Official Control of the Food Chain (PNCOCA), associated methods of analysis, reported results of the testing program, and additional official documentation outlining the structure of Spain's official chemical residue testing program. Spain's chemical residue plan is developed and implemented in compliance with EU and national requirements.

MAPA and MSAN develop the PNCOCA in accordance with Regulation (EU) 2017/625 and develop PNIR (it is included in PNCOCA with two specific programs: (1) in farms and (2) in food (Program 15)) in accordance with Commission Directive 96/23/EC. This directive is repealed by Regulation (EU) 2017/625 but is in force temporarily (Article 150 of Regulation (EU) 2017/625).

The PNIR includes a targeted plan and a suspicious plan which are samples generated for cause. The maximum limits of residues (MLR) are set in EU Regulations (Commission Regulation (EU) No. 37/2010 for veterinary drugs, Commission Regulation (EC) No. 1881/2006 for contaminants, or Regulation (EC) No. 396/2005 for pesticides among others). However, MSAN has developed a specific procedure in order to apply the United States MLR when they are stricter.

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 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 2022 sampling program was being implemented as scheduled.

The FSIS auditors verified Spain requires establishments to hold any products tested for chemical residues pending acceptable results from a laboratory's initial analysis. Each time a violative result is detected, MSAN implements a procedure for requiring 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 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 analysis and remote 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 and contaminants in pork products destined 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 pork products prepared for export to the United States are 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 audits. When a noncompliance is observed with the establishment's indicator organism testing program, MSAN issues a noncompliance report. If multiple recurring noncompliances are observed, MSAN can issue a NOID or the establishment approval to operate can be withdrawn. The FSIS auditors interviewed government personnel and reviewed records without identifying any findings with the verification and implementation of indicator organism testing requirements.

MSAN has adopted a zero-tolerance approach for *Lm* and *Salmonella* in RTE products which is consistent with FSIS policy. Testing is required by the OVs for official controls and establishments are to have a sampling program in place 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 utilized 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*. 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 and reviewed records that included government testing results and corrective actions regarding positive test results during the audit without identifying any findings with *Lm* and *Salmonella* 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 regulatory requirements regarding these parameters as well FSIS requirements. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings 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 products destined for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held June 17, 2022, by videoconference with MSAN. The FSIS auditors concluded that Spain's pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. MSAN has required that establishments certified as eligible to export pork products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, MSAN has implemented official microbiological and chemical residue testing programs that are organized by the national government to verify its food safety system. An analysis of each component did not identify any findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report

MINISTRY
OF HEALTH

SECRETARY OF STATE
FOR HEALTH

GENERAL DIRECTORATE
OF PUBLIC HEALTH

Michelle Catlin, PhD
International Coordination Executive
Office of Internacional Coordination
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Aveneu, SW
20250 Washington, D.C.

Dear Dr. Catlin,

In relation to the audit report related to the audit carried out from June 1 to 18, 2022 in Spain, received last September 3, we have detected some errors (mistakes):

- Regarding the table with the process category (*page 1*), the following two categories don't appear in this table:

Process Category	Product Category	Eligible Products	Establishment nº
Heat Treated-Shelf Stable	RTE Acidified/Fermented Meat	Sausage/salami – not sliced	43
Products with Secondary Inhibitors-Not Shelf Stable	NRTE otherwise processed meat	Sausages products	47

- Regarding establishments that participated in the audit, in the report appears establishment number 27 instead of the establishment 23. (*page 3*) The establishment No 23 is authorized as swine slaughterhouse as well as swine processing.

Swine processing establishment	1	• Establishment No. 27, Embutidos Fermín S.L., Tamames

- The scope of the audit (*page 2*) included two pork slaughter and cutting plants (establishments No 33 and 37) and one pork slaughter, cutting and processing plant (establishment No 23).

A sample of three establishments was selected for the remote audit from a total of 27 establishments certified to export to the United States. This included two pork slaughter and one pork processing establishment. The categories of pork products these establishments produce and

We thank you for taking into account our comments and correcting the detected errors.

If you have any questions, do not hesitate to contact us at saniext@sanidad.gob.es; exportacionsanidad@sanidad.gob.es; jtroncoso@sanidad.gob.es; tbarranco@sanidad.gob.es

Yours sincerely,

THE DEPUTY GENERAL MANAGER
Fernando Carreras Vaquer