



United States Department of Agriculture

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Food Safety and
Inspection Service

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Dear Dott. Putti,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of San Marino's meat inspection system from April 27 through June 2, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of San Marino 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,

A handwritten signature in blue ink, which appears to read "Michelle Catlin", is positioned above the printed name.

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
SAN MARINO

APRIL 27–JUNE 2, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
PORK MEAT PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

November 10, 2021

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) April 27–June 2, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using a combination of video conferences and records review. The purpose of the audit was to determine whether San Marino'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. San Marino currently exports fully cooked-not shelf stable, ready-to-eat pork products to the United States.

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 San Marino's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has implemented sanitation and HACCP system requirements to ensure controls of hazards in pork products. In addition, the CCA has implemented a microbiological testing program that is organized and administered by the national government to verify its food safety 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 San Marino's food safety inspection system from April 27–June 2, 2021. The audit began with an entrance meeting via videoconference on April 27, 2021, with representatives from the Central Competent Authority (CCA) - the Prevention Department (*Dipartimento Prevenzione*). Representatives from the Prevention Department participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that FSIS conducted remotely due to the COVID-19 pandemic. The audit objective was to determine whether San Marino's food safety inspection system governing pork products exported to the United States remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. San Marino is eligible to export the following products to the United States:

Process Category	Product Category	Eligible Products ¹
Fully Cooked - Not Shelf Stable	Ready-to-Eat (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

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes San Marino as free of African Swine Fever (ASF) and free of Foot-and-Mouth Disease (FMD) but with special restrictions. APHIS has also identified San Marino as affected with Classical Swine Fever (CSF) and Swine Vesicular Disease (SVD). As such, pork product imported from San Marino is subjected to CSF requirements specified in 9 CFR 94.9, Swine Vesicular Disease SVD requirements specified in 9 CFR 94.12, and FMD requirements specified in 9 CFR 94.11.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed the Prevention Department's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether San Marino'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 analyses of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the Prevention Department through the SRT and technical discussions.

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

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 at the Prevention Department headquarters as well as government verification records from the only local inspection office. The FSIS auditors evaluated through records review the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The audit included the sole establishment in San Marino that the Prevention Department has certified as eligible to export to the United States. The products this establishment is eligible to produce and export to the United States include RTE, fully cooked-not shelf stable pork.

This remote audit focused on a review of records associated with official government verification activities conducted at the establishment. It did not include a review of establishments' conditions or records. The FSIS auditors assessed the Prevention Department's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

The FSIS auditors also remotely audited one government microbiological testing laboratory to verify that the laboratory provides adequate technical support to the food safety inspection system.

Remote Audit Scope	#	Locations
Central Competent Authority	1	<ul style="list-style-type: none"> Prevention Department headquarters, San Marino
Laboratory	1	<ul style="list-style-type: none"> Public Health Laboratory (government microbiological), San Marino
Pork processing establishment	1	<ul style="list-style-type: none"> Establishment No. 2L, San Marino Salumi s.r.l., San Marino

FSIS performed the remote audit to verify that the 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.*); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of San Marino'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 (SPS Agreement)*.

III. BACKGROUND

From December 1, 2017 to November 30, 2020, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 182,834 pounds of RTE pork products exported by San Marino to the United States. Of these amounts, additional types of inspection were performed on 19,941 pounds of pork, including physical examination and testing for microbiological pathogens (*Listeria monocytogenes [Lm]* and *Salmonella* in RTE products). FSIS did not reject any shipments from San Marino of pork products for issues related to public health as a result of this additional testing.

The prior FSIS audit in 2019 identified the following systemic findings:

Summary of Systemic Findings from the 2019 FSIS Audit of San Marino	
Component Three: Government Sanitation	
<ul style="list-style-type: none"> The CCA did not document verification of San Marino's requirements in Directorate General for Food Hygiene, Food Safety and Nutrition (<i>DGISAN</i>) 35665 for handwashing to prevent <i>Listeria monocytogenes</i> in RTE establishments. 	
Component Four: Government Hazard Analysis and Critical Control Point (HACCP) System	
<ul style="list-style-type: none"> The CCA's inspection system failed to ensure compliance with HACCP requirements including: <ul style="list-style-type: none"> lack of ongoing verification procedures and frequencies in the HACCP plans, a repeat finding; failure of the establishment to document the type of ongoing verification activity and results of the verification activity in HACCP records, a repeat finding; and the establishment's critical control point (CCP) monitoring records did not include actual values obtained at the time of monitoring. 	

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

The FSIS recent final audit reports for San Marino'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.

San Marino's Ministry of Health oversees the public service governmental structure known as the Social Security Institute (Istituto per la Sicurezza Sociale [ISS]). One of the critical services provided by the ISS is health care to the citizens of San Marino. The ISS is composed of the following three departments: the Prevention Department (Dipartimento Prevenzione), the Social and Health Department (Dipartimento Socio Sanitario), and the Hospital Department (Dipartimento Ospedaliero). The Prevention Department is responsible for food safety and inspection of meat products and export controls.

The food safety control measures in the one establishment in San Marino that is eligible to export to the United States are governed by multilayered regulatory oversight including laws, regulations, decrees, and departmental protocols. San Marino has adopted all European Union (EU) regulations and directives applicable to its inspection system in accordance with the *EU-San Marino Trade Agreement of 1994*. The Prevention Department responds to any amendments, annulments, or new issuances in EU regulations or directives by making required adjustments.

Based on the information provided in the SRT and information gathered through previous onsite audits, the Prevention Department is structured into the following two Complex Operative Units (Unità Operative Complessa [U.O.C.]): the Complex Operative Unit of Public Health (U.O.C. Sanita Pubblica) and the Complex Operative Unit of Occupational Safety and Health (U.O.C. La Sicurezza e la Salute sul Lavoro). The U.O.C. Sanita Pubblica is divided into the following Simple Operative Units (Unità Operativa Semplice [U.O.S.]): Simple Operative Unit of Veterinary Health and Food Hygiene (VHFH), (U.O.S. Sanita Veterinaria e Igiene Alimentare), the Simple Operative Unit of Public Health Laboratory (U.O.S. Laboratorio di Sanita Pubblica) referred to hereafter as the Public Health Laboratory, and the Simple Operative Unit Protection of Natural and Built Environment (U.O.S. Tutela Dell'ambiente Naturale e Costruito). The Prevention Department is headed by the Director who is responsible for communication in matters of meat and other food products exported from San Marino to the United States.

The VHFH provides routine veterinary inspection and supervision at the only establishment eligible to export to the United States. The VHFH is comprised of the head of the unit and four fully trained veterinarian inspectors. The head of the unit reports directly to the director of the Prevention Department and supervises the four veterinarian inspectors. The FSIS auditors verified that there have not been any changes in San Marino's inspection system since the prior FSIS audit in 2019 or from the information provided in the SRT submissions.

The Prevention Department has the authority and responsibility to enforce the laws and regulations governing meat and has the authority to certify establishments eligible to export to the United States in accordance with Article 9 of *Law No. 85 of 29 October 1992, Regulation of Hygiene in the Production, Storage, Transport, Sale and Administration of Food and Beverages*. Although San Marino is not a member of the EU, under the terms of *Decision 1/94 of San Marino-CE Cooperation Committee*, San Marino has adopted EU regulations to protect

consumer and animal health. In addition to the EU's overarching regulations, the Prevention Department provides procedural guidance or instructions by periodically issuing Protocols (*Prot.*) documents when needed. One of the many objectives for the issuance of a *Prot.* document is to provide guidance to inspectors on procedures for meeting non-EU countries requirements or serving as a medium of communication among the Prevention Department as well as domestic and foreign entities. *Prot. No. 3169/DPS-V2/2017, Official Controls at the Establishment Registered in the List of Plants Authorized to Export Meat Products in the USA* (referred to hereafter as *Official Controls USA*), includes instructions for government inspection personnel to verify the establishment eligible to export to the United States complies with requirements consistent with 9 CFR Parts 416, 417, 430, and all other relevant regulations. *Annex A, Manual for the Performance of Official Controls in the Assessment of Compliance with US Regulations*, of *Prot. No. 3169/DPS-V2/2017* contains specific government procedures to ensure compliance with equivalence requirements (referred to hereafter as *Manual for Official Controls USA*).

San Marino sources its raw pork meat used in RTE products destined for the United States from eligible establishments in other countries eligible to export to the United States. This requirement for sourcing raw material is grounded in *Prot. No. 7969 /DSP V2/2017, Compliance with US Export Purposes – Source Material*. The traceability of products of animal origin entering or leaving San Marino is enforced per *Decree No. 59 of 20 May 1996, Rules Relating to Veterinary Controls Applicable in Exchanges of Live Animals and Products of Animal Origin*. In cases where traceability of products of animal origin is in doubt, inspectors take samples as part of an investigation. This may include reviewing Europe's Rapid Alert System for Food and Feed (RASFF) portal to ensure the product has not been implicated in a food safety alert. If the product under investigation tests positive for the presence of pathogens, chemical residues, or any environmental contaminants, the food business operator (FBO) can initiate a product recall, or in the absence of an FBO's action, the Prevention Department can use its legal authority to seize, detain, or destroy the product. Although not directly related to this sub-criterion, the Prevention Department shared an example of product seizure and destruction under *Prot. No. 3889 /DSP-V2/2019*, dated July 1, 2020, *Seizure and Destruction of Food Products (Sequestro e Distruzione prodotti alimentari)*, pursuant to Article 9 of *Law No. 85*.

Specific provisions in *Delegated Decree No. 71 of 29 June 2012, Specific Hygiene for Foods of Animal Origin*, grant legal authority to the Prevention Department to certify a food business upon inspection of the facility and determination of compliance of the requesting facility with applicable laws and regulations. Additionally, the Prevention Department has procedures to list or delist establishments from the list of certified establishments eligible to export to the United States. However, the FSIS auditors were not able to verify an example of these procedures, as San Marino has not certified any new establishment or changed the eligibility of the sole certified establishment.

The FSIS auditors reviewed documents to establish the way communication flows from the management level down to the inspection staff, especially how information on FSIS requirements are channeled to the inspectors assigned to the establishment eligible to export to the United States. New information received at the Prevention Department from FSIS is first analyzed and then sent via e-mail through the supervisory chain of command to the inspectors.

The e-mail is followed by hard copies, which are printed and provided to the inspection staff. The FSIS auditors verified that the Prevention Department maintains mechanisms to disseminate any new information to inspection officials and the establishment in a timely manner.

In San Marino, the inspection system is comprised of only full-time government employees who have successfully completed all phases of recruitment requirements, including written and oral tests, to enter the civil service. The minimum educational requirement for a veterinarian to be hired into the Prevention Department is a Doctor of Veterinary Medicine or an equivalent degree. For auxiliary inspection staff, an employee must have completed at least three years of college-level work. Additionally, veterinarians undergo on-the-job training designed specifically to conduct inspection duties at establishments eligible to export to the United States. A range of topics are covered during the training, including food and feed regulations, HACCP system requirements, audit, and inspection techniques. San Marino, being signatory to the *EU-San Marino Agreement of 1992*, requires its official veterinarians and official auxiliary staff to meet the EU's minimum educational and training requirements. *Prot. No. 1125/DSP-V2/2016, Plan of Official Controls on Food Safety*, provides requirements for training of the inspectors in the field of feed and food safety. The Prevention Department arranges participation of its staff in trainings offered by the EU and by the Italian Ministry of Health. The FSIS auditors concluded that inspectors receive ongoing training and maintain their veterinary accreditation by earning continuing education credits through participation in seminars, conferences, and the Prevention Department's organized training. Due to the COVID-19 pandemic, the annual training plan for 2020 did not transpire but will be resumed in 2021.

The documents reviewed and interviews conducted by the FSIS auditors indicate that only inspectors paid and hired by the government are assigned to the establishment eligible to export to the United States. The FSIS auditors further established that the Prevention Department prohibits situations resulting in conflicts of interest as prescribed in *Prot. No. 1125/DSP-V2/2016, Plan of Official Controls on Food Safety* and subsequent updates of the document.

The FSIS auditors' reviews included the assessment of the Prevention Department's standards and policies on guaranteeing inspection service at least once per production shift when the establishment processes pork meat products intended for export to the United States. Specific provisions to ensure "once per production shift inspection coverage" are described in *Official Controls USA* and *Prot. No. 8405/DSP V2/2017, Compliance for U.S. Export*, and are analogous to FSIS regulatory requirements consistent with 9 CFR Part 307.4. The establishment notifies the VHFH via e-mail well in advance of expected arrival of shipments of raw material to be used in manufacturing products destined for export to the United States. The e-mail notification also includes schedules for the various processes. Interviews conducted with the inspection staff, in conjunction with review of records ranging from e-mails, samples of health certificates, documents associated with incoming raw product, and corresponding inspector's *Routine Verification Checklists (Scheda Di Controllo – 6.1, modulistica Controllo Routinario Rev. 1)*, indicate a documented system of inspection ensuring that each lot destined for export to the United States is prepared under VHFH supervision. The official veterinarian (OV) ensures that the sourced raw meat product is from an eligible source and meets APHIS and EU animal health requirements by reviewing health certificates and shipping documents accompanying the product received at the establishment. Furthermore, the FSIS auditors examined a series of *Routine*

Verification Checklists to corroborate the date of lots of shipment received at the establishment with that of the inspector's verification activities on those dates. No concerns arose as a result of the FSIS auditors' verifications.

The FSIS auditors' interviews and review of documents confirmed that the Prevention Department maintains procedures for product traceability, procedures for product recall, and mechanisms to notify FSIS when adulterated product has been shipped to the United States. The Prevention Department requires the certified establishment eligible to export to the United States to develop and implement recall procedures in accordance with *Prot. No. 3649/DSP-V2/2019, Sanitary Provisions for Food Products Intended for U.S. Export (Disposizioni sanitarie per prodotti alimentari destinati all'export USA)*. The FSIS auditors further verified that the Prevention Department was maintaining procedures per *Prot. No. 0310UOS2014, Recall Procedure for Adulterated Product (Procedura di richiamo prodotto adulterate)* to notify FSIS if adulterated product has been shipped to the United States.

The Public Health Laboratory is a government laboratory managed by the Prevention Department. The laboratory provides full technical support related to microbiological testing within San Marino's meat inspection system. The Prevention Department relies on third-party accreditation to ensure that the Public Health Laboratory conforms to and maintains its operating procedures in accordance with the International Organization for Standardization (ISO) Guide 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*. The laboratory was last audited by ACCREDIA (*L'Ente Italiano di Accreditamento*), an Italian based accrediting body, in 2015. Although the laboratory's term of accreditation granted by ACCREDIA expired in February 2017, the laboratory continues to implement operating procedures consistent with ISO 17025 standards. The laboratory staff are not technically qualified to carry out internal audits; therefore, the Prevention Department hires ACCREDIA-certified auditors to accomplish these "internal audits" to ensure the laboratory is adhering to ISO 17025 standards. The most recent "internal audit" was conducted in April 2019 by one such certified auditor. The FSIS auditors reviewed the audit report, *Rapporto di Audit Interno*, from their most recent "internal audit," and the audit scope included the analytical methods *Microbiology Laboratory Guidebook (MLG) 4.10 for Salmonella spp.* and *MLG 8.11 for Listeria monocytogenes and Listeria spp.* The Public Health Laboratory addressed the observations or recommendations made by the auditor in the report. The FSIS auditors verified the ACCREDIA certification of the auditor that conducted the "internal audit" in April 2019.

The FSIS auditors reviewed the laboratory's project to resume ACCREDIA certifications, which was approved by the General Directorate on December 11, 2020. The project allocates the financial resources needed to resume ACCREDIA inspections by 2021; however, the project has been delayed until March 2022 due to the COVID-19 pandemic. As part of the project, the Prevention Department contracted a Rome-based consulting and auditing body, ANGQ (*National Association for Quality Assurance*) Sistemi, to audit the laboratory for its compliance with ISO 17025:2005 requirements. ANGQ Sistemi will also be tasked with training the technical staff to bring the laboratory into compliance with ISO 17025:2017 standards prior to the ACCREDIA audit scheduled to take place in early 2022.

Pertaining to the laboratory's calibration and maintenance program, (*Programma tarature e manutenzioni*), the FSIS auditors verified a sample of records including the *Equipment Identification Sheet (Scheda Identificativa Apparecchiatura)* and the *Equipment Calibration and Maintenance Sheet (Scheda di taratura e manutenzione)*. The review concluded that these laboratory worksheets were completed and maintained in accordance with procedures outlined in the *Procedura Gestionale 04 Rev. 8*. Interviews conducted with the head of the Public Health Laboratory revealed the laboratory is in the process of upgrading its Laboratory Information Management System (LIMS) and the upgrade is expected to be completed in June 2021 followed by staff training of the new system. At full functionality, all records will be maintained electronically. FSIS auditors also reviewed documents and conducted interviews related to sample receipt, integrity, analysis, quality controls, analyst competence, proficiency testing, training, and maintenance of laboratory accreditation. None of the laboratory's functions reviewed or discussed in interviews with the head of the laboratory raised concerns.

Lastly, the Prevention Department presented its five-year plan, the *Integrated National Control Plan (Piano Dei Controlli Ufficiali Sulla Sicurezza Alimentare [PNI 2021-2025])*, which outlines the system of official controls on food, feed, health, and animal welfare with the aim of verifying compliance with the relevant legislation, preventing risks to public health and protecting consumer interests. The *PNI 2021-2025* identifies general strategic objectives, including strengthening food safety controls, consumer health protection, environmental contamination in relation to agro-zootechnical production, and the protection of animal health and welfare. Each year, the plan is reevaluated and adjusted for improvement.

The FSIS auditors verified that the Prevention Department's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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

The scope and frequency of periodic supervisory visits at the establishment eligible to export to the United States are laid out in *Official Controls USA*. The scope of the supervisory review includes the export certification process, official controls over establishment construction, facilities, and equipment, sanitation standard operating procedures (Sanitation SOPs), HACCP, and other programs in accordance with FSIS requirements. The elements of supervisory reviews are organized in the *Supervisory Checklist (Scheda di Supervisiones Rev.3)* document. The Prevention Department conducts a minimum of four supervisory visits per year but may increase to a higher frequency, if warranted. The *Supervisory Checklist* documents the results of the supervisory review into two parts: (1) an assessment of the establishment's compliance with

FSIS export requirements, and (2) an evaluation of the inspector's performance.

The FSIS auditors reviewed documentation of the supervisory visit conducted on February 22, 2021. The visit included shadowing the OV to assess the OV's performance. Multiple sanitation performance standard (SPS)-related noncompliances were identified and documented by the OV. The visit also included document review related to the critical control points (CCPs), the establishment's microbiological testing programs, as well as microbiological test results. The FSIS auditors reviewed the noncompliance record that was issued on the date of the supervisory visit for the SPS noncompliances observed. Due to the maintenance work involving funds approval from establishment management, the noncompliance took longer than usual to resolve but was finally closed on March 22, 2021. The supervisory report did not identify any concerns regarding the performance of the inspector. Although there have been no recent instances that required an adverse action against the inspector's performance, the inspection system has a method to deal with situations when the inspector's performance requires immediate action to remedy the problem. Performance-related deficiencies are documented under the *Prescriptions to the Official Veterinarian (Prescrizioni al Veterinario Ufficiale)* and a copy indicating an estimated date of correction is sent to the responsible head of the VHFH.

The FSIS auditors verified through review of records that the Prevention Department requires the establishment producing product intended for export to the United States to provide complete separation of product from that intended for other foreign or domestic markets. These requirements are issued in both *Prot. No. 2407/2009, Products Intended for the United States*, and *Prot. No. 8405/DSP V2/2017, Compliance for U.S. Export*, which direct establishments to meet the conditions either of time or space to maintain separation when it intends to produce products for export to the United States. Some of the practices employed by the establishment to achieve the requirements include the following: the production shift begins by processing products for export to the United States, if the raw products for exports are available; the use of dedicated racks and coolers; and lot identifications are maintained throughout processing departments. Based on documents examined and the discussions held with the OV, the FSIS auditors concluded the Prevention Department ensures that the establishment meets requirements of providing complete separation when products intended for export to the United States are prepared and stored in accordance with the instructions in *Prot. No. 2407/2009* and *Prot. No. 8405/DSP V2/2017*.

There are no pig farms in San Marino; therefore, the country does not operate any slaughter establishments and instead sources its raw pork products from eligible slaughter establishments in Italy and Denmark. Additionally, the Prevention Department is not eligible to export raw pork products to the United States due to APHIS animal health restrictions. The Prevention Department ensures that each shipment of raw pork product arriving into San Marino meets APHIS requirements as stipulated in 9 CFR Part 94. The FSIS auditors verified that the OV routinely checks the health certificates of incoming raw pork product and corroborates the seal information on the truck with the information on the shipping document. Prior to export certification, the OV ensures compliance with APHIS requirements, including during deboning and heat treatment to ensure the internal product temperature of 69°C (156.2°F) is met. The compliance with APHIS requirements is also captured during supervisory visits as evidenced from reviews of a sample of supervisory checklists.

Under the provisions in Annex II of *Delegated Decree No. 70 of 29 June 2012, Food Products Hygiene*, the inspection system requires establishments to put procedures in place to identify, segregate, and properly dispose of inedible materials to prevent the use of any condemned food waste in products intended for export to the United States. Additional requirements are laid out in *Prot. No. 3649/DSP-V2/2019, Sanitary Provisions for Food Products Intended for United States Export (Disposizioni sanitarie per prodotti alimentari destinati all'export USA)*, which states that inedible materials need to be kept in a lockable container with conspicuously placed “inedible” signs. Additionally, establishments are required to maintain control of these containers of inedible materials and keep records of the description and weight of the inedible products collected. Prior to moving condemned materials away from the establishment’s premises, they are denatured with dye either by the OV or the designated establishment employee. *Prot. No. 8405/DSP V2/2017* contains instructions for the OV regarding verification tasks to be conducted to ensure that inedible products are not used for products destined for export to the United States. The FSIS auditors did not identify any concerns through documents reviewed and interviews with the government inspection officials.

The FSIS auditors also verified the Prevention Department’s labeling requirements and verification activities to ensure that only properly labeled products are inspected and passed for export to the United States. San Marino’s definition of food adulteration lies in Article 6 of *Law No. 85 of 29 October 1992, Rules of Hygiene in Supply of Food and Drinks*, which also prohibits establishments from possessing, selling, using, or administering adulterated foods for human consumption. Additional prohibitions on misleading labels to consumers are contained in Article 14 of *Delegated Decree No. 68 of 29 June 2012, General Requirements for Food Safety*. Article 14 authorizes the Prevention Department to take appropriate measures, including product seizure and destruction, if adulterated or misleading labeled product enters commerce.

Label verification instructions for OV are found in *Manual for Official Controls USA* and are consistent with the regulatory requirements prescribed 9 CFR Part 317.2. The OV verifies these requirements on incoming raw pork products and at time of export certification to ensure product for export to the United States meets requirements consistent with 9 CFR Part 317.2 in its entirety. The FSIS auditors verified records for two types of RTE cooked ham products (*Dolcecolle USA and Gusto Vincente with herbs*). Labels currently in use for Dolcecolle products received approval from FSIS’ Labeling and Program Delivery Staff on June 23, 2008. The FSIS auditors also reviewed ingredients information by third-party suppliers and generically approved labels of similar RTE cooked ham products. The establishment’s compliance with labeling and whether OVs are conducting labeling verification activities in accordance with *Manual for Official Controls USA* are also captured during supervisory reviews. No concerns arose as a result of the FSIS auditors’ review.

The FSIS auditors verified that the Prevention Department has the legal authority to establish regulatory controls over meat establishments that are eligible to export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The

FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions and to include requirements for sanitation performance standards (SPS).

Article 4, Chapter 1 of *Decree No. 32 of 9 March 2005, Hygiene Regulations for Food Products*, is exclusively devoted to the requirements of Sanitation SOPs. It mandates that FBOs must develop, implement, maintain, and validate sanitation plans for before and during operations, and must include a recordkeeping system and corrective actions. *Delegated Decree No. 70/2012 Food Product Hygiene* vests legal authority in the Prevention Department to require FBOs in San Marino to implement sanitation measures and maintain hygienic conditions throughout their operations. The specific provisions in the decree hold FBOs responsible for ensuring food hygiene through maintaining sanitation of the facility, equipment, and personnel hygiene. Provisions in Annex II of *Delegated Decree No. 70/2012* specify general requirements for design, structure, ventilation, plumbing, drainage, supply of potable water, and pest control to prevent product adulteration and are applicable to all FBOs. These requirements are consistent with FSIS SPS regulations found in 9 CFR Part 416. FBOs found in violation with sanitation and hygiene regulations are charged with penalties including citations carrying monetary fines. Administrative sanctions are applicable under Article 9 of *Law No. 85 of 29 October 1992* when an FBO fails to follow its hygiene plan or is determined to be in violation with the food hygiene regulations.

Prior to January 22, 2020, the establishment certified to produce RTE pork for export to the United States was operating under requirements consistent with *Listeria* Alternative 3 to control *Listeria*. The establishment prevented the pathogen through sanitation programs in conjunction with implementing a testing program to sample food contact surfaces (FCS) in the post-lethality processing environment in accordance with the Italian Circular *DGISAN 42841-25/06/2019: Listeria monocytogenes and Salmonella spp. in Pork Products Eligible to be Exported to the United States of America - Criteria and Management of the Plant Self Control and Competent Authority Verification Methods*. Per this document, establishments are required to verify sanitation by testing FCS for *Lm* or indicator organisms and are to develop a surveillance program to detect *Lm* in the RTE products. The document also underscores the specific sanitary practices, particularly for employee hygiene measures, such as washing and sanitizing hands and establishing the frequency for using disposable gloves prior to entering post-lethality exposed (PLE) production areas. The FSIS auditors verified through document review and pictorial demonstration that the implementation of corrective actions to address the 2019 FSIS audit finding related to the establishment's failure to adhere to employee hygiene per Italian Circular *DGISAN 35655-P-16/09/2015* (now replaced by *DGISAN 42841-25/06/2019*) was effectively corrected.

The Prevention Department, through *Official Controls USA*, requires establishments eligible to export to the United States to develop and implement procedures for sanitation to meet requirements consistent with FSIS requirements in 9 CFR 416. The protocol also provides instructions to inspectors on verification of sanitation requirements. The *Manual for Official Controls USA* details these instructions and provides checklists for inspectors to follow as they verify sanitation requirements in the establishment eligible to export to the United States. The government verification tasks are consistent with FSIS sanitation requirements for SPS and

Sanitation SOPs as stipulated in 9 CFR 416. The official controls checklist consists of verification of regulatory requirements for SPS as well as Sanitation SOPs through document review, observation, and hands-on activities. While verifying Sanitation SOPs, inspectors ensure operational as well as pre-operational sanitation are adequately addressed, and corrective actions are reviewed for effectiveness and their ability to prevent recurrences. The OV's *Routine Verification Checklists* and the associated non-conformities reports reviewed by the FSIS auditors indicate that operational sanitation is verified during each processing shift and the inspector performs the pre-operational sanitation verification task at least once every month, when the establishment produces product for export to the United States. The FSIS auditors also verified that the OV is present during production of each lot, including for export certification.

Official Controls USA also provides instruction for the supervisors for verifying establishment compliance with the sanitation requirements. The scope of the supervisory review in relation to the establishment's sanitation program includes evaluation of SPS, Sanitation SOPs, document review, and an onsite visit accompanying the OV. The outcome of the reviews is documented in the *Supervisory Checklist (Scheda Di Supervisione Rev.3)*, which comprises a checklist for verifying an establishment's compliance with requirements for SPS and Sanitation SOPs consistent with FSIS requirements. Supervisory visits may include pre-operational verification based on risk or emerging trends.

San Marino's meat inspection system continues to maintain regulatory requirements for sanitation in establishments certified to export to the United States, which as described, is consistent with criteria established for this component.

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.

The requirements for the development, implementation and maintenance of a HACCP system are laid out in Chapter II, Article 5 of *Decree No. 32/2005 Hygiene Regulations for Food Products*, which requires FBOs to develop a HACCP system based on the seven principles of HACCP. Establishments need to conduct a hazard analysis, identify CCPs and critical limits, establish monitoring and verification procedures, and establish a corrective action plan when a deviation from a critical limit occurs. The requirements of the decree apply to all food handling business in San Marino irrespective of their eligibility to export to foreign markets. Additional requirements for the development of a HACCP system are prescribed in Articles 1 and 5 of *Delegated Decree No. 70/2012*. Chapter XII of Annex II of *Delegated Decree No. 70/2012* mandates that FBOs acquire training in Sanitation SOP and HACCP principles.

The Prevention Department, through *Official Controls USA*, requires establishments eligible to export to the United States to develop and implement procedures for Sanitation SOPs, HACCP, and *Listeria* controls consistent with FSIS regulatory requirements stipulated in 9 CFR Parts 416, 417, and 430, respectively. The protocols provide step-by-step procedures that correspond to the

regulatory requirements for sanitation, HACCP, and *Listeria* control cited above without prejudice to EU regulations, which San Marino has adopted under the *EU-San Marino Trade Agreement of 1994*.

Per *Prot. No. 8405/DSP V2/2017, Compliance for US Export*, the Prevention Department integrated HACCP requirements for RTE establishments contained in the Italian Circular *DGISAN 42841-25/06/2019*, which is consistent with FSIS regulatory requirements, directives, and compliance guidelines for control of *Lm* and *Salmonella* in RTE products.

The document review related to HACCP verification and the discussion held with the government officials indicated that the establishment certified to export to the United States reassessed its HACCP plan and made changes to control the *Lm* hazard in its post-lethality production environment. Prior to January 2020, the establishment addressed the biological hazard of *Lm* through *Listeria* Alternative 3, using a sanitation program in conjunction with testing of FCS, environment, and product. The establishment then had an *in situ* third-party study conducted to conclude that the post-lethality process applied could achieve 4-log₁₀ reduction of *Lm* in the product. A request to the Prevention Department from the establishment to switch from *Listeria* Alternative 3 to Alternative 2A (Post-lethality Treatment) was granted upon a favorable review of the study and the completion of a 90-day in-plant process validation. The inspection officials shared the communications that took place between the establishment and the Prevention Department and provided the copy of the scientific study conducted by the third-party (*Zooprophylactic Institute of Brescia*) that included the in-plant validation to support the establishment moving from *Listeria* Alternative 3 to 2A.

The FSIS auditors reviewed the design and execution of the certified establishment's revised HACCP plan, which was verified by the OV on May 21, 2021, and confirmed that the establishment had considered all hazards associated with its PLE, RTE fully-cooked pork operations. Packaged cooked ham products are subject to a post-lethality treatment comprising hot water pasteurization at 120 °C (248 °F) for 15 minutes. Other validated time and temperature combinations are used for other products like half cut hams. Prior to the current revision of the HACCP plan, the hazard of spore germination during product stabilization was addressed through a CCP. However, the latest hazard analysis took into consideration the historical data collected over the years that supports addressing the hazard through a prerequisite program rather than by a CCP. The establishment incorporated stabilization performance standards outlined in Appendix B of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products* into its prerequisite program for the cooling phase. The documents reviewed demonstrated the revised changes in the hazard analysis, HACCP plan, and measures applied to control *Listeria* in post-lethality production areas were verified by the OV.

The FSIS auditors further verified through record review and interviews that the OV conducted regular verification of HACCP-related procedures as required by *Official Controls USA*. HACCP verification activities by the OV include the evaluation of written HACCP programs, establishment's monitoring and verification activities, corrective actions, recordkeeping, hands-on evaluation of CCP, and pre-shipment reviews. The FSIS auditors cross-checked a set of documents related to lots that were exported to the United States with the OV's *Routine Verification Checklists* and concluded the verification covered all aspects of the establishment's

HACCP system and, when detected, noncompliances were documented on the noncompliance report, *Scheda Delle Non Confirmita*.

The FSIS auditors verified the supervisory reviews pertaining to HACCP system requirements are conducted within the required frequency and are comprised of document review and onsite visits to the establishment. These reviews are documented on the *Supervisory Checklist*, and, as previously mentioned, also require evaluation of the OV's performance. The FSIS auditors determined that HACCP system compliance is verified and documented by the OV as well as by the supervisor in accordance with the *Official Controls USA* and is consistent with the HACCP and *Listeria* controls requirements in 9 CFR Parts 417 and 430, respectively.

The Prevention Department requires the establishment eligible to export to the United States to address the presence of *Trichinella spiralis* in incoming raw pork used to process RTE pork product for export to the United States. The FSIS auditors verified through document review that the establishment has addressed the risk of product containing *Trichinella* through letters of guarantee. The FSIS auditors verified that the OV routinely reviews shipping documents to ensure product safety and wholesomeness.

Through document review and interviews with the inspection officials, the FSIS auditors verified that the corrective actions taken in response to the 2019 FSIS audit findings related to the HACCP system were effective in resolving the issues.

The FSIS auditors verified through interviews and record review that the Prevention Department requires establishments certified to export to the United States to develop, implement, and maintain HACCP systems.

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 include a chemical residue testing program, organized and administered by the national government, for random sampling of internal organs, fat, and muscle of carcasses to test for chemical residues identified as likely contaminants by the exporting country's meat products inspection authorities or by FSIS.

The Prevention Department does not maintain its own chemical residue monitoring program for swine animals because there are no hog farms in San Marino and there are no establishments eligible to conduct swine slaughter for export to the United States. To meet the requirements of this component, San Marino relies on the chemical residue testing program of the countries from which it sources its raw pork products. The documents reviewed by the FSIS auditors indicate that the sole eligible establishment had sourced its supply of raw pork from certified establishments located in Italy and Denmark. The official verification activities involve routinely reviewing the chemical residue monitoring results of these countries as well as Europe's RASFF. Additionally, the Prevention Department verifies that the certified establishment maintains an open line of communication with the United States-eligible slaughter establishments in Italy and Denmark.

Through document review and interviews conducted with the OV, the FSIS auditors verified that the government inspection personnel ensure that the establishment follows the control measures identified in its HACCP plan to address hazards associated with chemical and environmental contaminants on incoming raw pork meat products.

The OV, as part of the assigned verification tasks, reviews the shipment's accompanying documents including health certificates and checks the supplying establishment's eligibility by visiting the United States foreign establishments' eligibility website. Additionally, the OV reviews the RASFF to ensure the supplying establishment is not implicated in any food safety recalls or other adverse events.

Through interviews and record reviews, the FSIS auditors verified that the Prevention Department is meeting the core requirements of this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth 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 verify that meat products prepared for export to the United States are safe and wholesome.

The Prevention Department adopted the procedures and requirements contained in the Italian Ministry of Health's Circular *DGISAN 42841-25/06/2019* to establish microbiological testing criteria and official verification activities for its inspection system governing the only establishment eligible to produce RTE, fully-cooked pork products for export to the United States. The Italian Circular *DGISAN 42841-25/06/2019* addresses requirements for lethality, stabilization, and, for RTE products exposed to the post-lethality environment, sampling of RTE product and FCS. The requirements in the circular mandates zero tolerance for *Lm* and *Salmonella* in RTE products and requires controls for *Lm* similar to those specified in 9 CFR Part 430. Although the Italian Ministry of Health has repealed and replaced this circular with *Ministerial Note 37041 of 21/10/2020 (Listeria monocytogenes e Salmonella spp. nei prodotti a base di carne suina destinati all'export negli USA - Criteri e modalità di gestione dell'autocontrollo aziendale e modalità di verifica dell'Autorità Competente)*, the new document does not require the Prevention Department to make any immediate changes to its RTE inspection program. The major change in the new ministerial note is centered around not-ready-to-eat (NRTE) products, which San Marino is not currently eligible to export.

In accordance with the definition of product adulteration in Circular *DGISAN 42841-25/06/2019*, RTE pork products exposed to post-lethality environments containing *Lm* or *Salmonella* are adulterated. In addition, the Prevention Department, through Circular *DGISAN 42841-25/06/2019*, requires that the establishment have validated support for *Salmonella* lethality, ensuring at least a 5-log₁₀ reduction and stabilization to ensure no more than a 1-log₁₀ multiplication of *Clostridium perfringens* and no multiplication of *Clostridium botulinum* in RTE meat products. Circular *DGISAN 42841-25/06/2019* incorporates provisions consistent with

FSIS Appendices A for lethality and B for stabilization for the validation by establishments exporting RTE meat products to the United States of cooking and cooling processes, respectively. Through interviews and document review, the FSIS auditors confirmed that the OV routinely verifies the implementation of the establishment's microbiological testing program. By utilizing specific sections of the checklist dedicated to the establishment's microbiological testing program, the OV verifies that the establishment follows its testing program in accordance with the protocols cited above.

The Prevention Department implements an annual microbiological testing program, which comprises product testing for *Lm* and *Salmonella*, as well as testing of the production environment for *Listeria* species to verify whether the establishment maintains sanitary conditions and complies with the government's requirement of zero tolerance for these pathogens. The Prevention Department provides these annual testing plans to FSIS on or prior to May 18 of each year. The documents reviewed by the FSIS auditors related to the requirements of microbiological testing frequencies, sampling matrices and sites, and analytical methodologies are governed by the instructions contained in Circular *DGISAN 42841-25/06/2019*.

The FSIS auditors confirmed through the review of microbiological testing data that the official testing programs are implemented in accordance with the testing frequencies outlined in Circular *DGISAN 42841-25/06/2019*. Samples are collected by the OV under three different sampling plans for products, food contact surfaces, and the production environment, and are as follows: RTE PROD_RAND and RTE PROD_RISK for products and Routine Lm Risk-Based (RLm) Sampling Program for sampling of products, FCS, and the environment. It is worth noting that the official testing frequencies have changed since January 2020, due to a change in the establishment's control measures to address *Lm* from *Listeria* Alternative 3, which relies solely on sanitation practices, to *Listeria* Alternative 2A, use of a post-lethality treatment to control *Lm*. Prior to the change, the Prevention Department maintained its testing frequency based on frequencies established for FBOs processing RTE meat products for export to the United States under *Listeria* Alternative 3. The FSIS auditors requested testing data for the period prior to as well as the period after the change and confirmed that government testing was conducted at the frequencies as defined for the respective alternatives.

The FSIS auditors reviewed the official letter *Prot. No. 335 DSP-V2/20 Official Sampling Plan for 2021* regarding the official RTE sampling plan for 2021 at the establishment eligible to export RTE cooked pork products to the United States. The FSIS auditors noted that the Prevention Department has scheduled official sampling and testing of both PLE and non-post-lethality exposed products for *Lm* and *Salmonella* and of environmental surfaces for *Lm* during the RLm. The RLm is comprised of a single sample unit consisting of 10 FCS, three indirect FCS, two non-FCS (environment), and five product samples from the same lot. The OV collects FCS samples both prior to operation and during the operation at the ratio of 30% pre-operative to 70% operative surface samples. The OV is responsible for collecting 100 grams of product for a 25-gram test portion to be analyzed for *Lm*, and concurrently collecting another 500 grams of product so that a 325-gram sample can be analyzed for *Salmonella*. Surface samples are collected from an area of at least 30 cm x 30 cm (900 cm²).

For maintaining microbiological independence between lots of product destined for export to the

United States, *Manual for Official Controls USA* provides the definition of a lot. A “lot” is defined as product manufactured between two pre-operative sanitations (clean-up to clean-up) that are microbiologically independent from each other. The Prevention Department requires establishments to hold lots of meat products subject to government sampling and testing pending test results. As stated before, and in accordance with Circular *DGISAN 42841-25/06/2019*, RTE products that contact a positive surface for *Lm*, *Salmonella*, or other pathogens or toxins are considered adulterated. Likewise, RTE product or FCS tested positive for *Listeria* species or *Listeria*-like organisms are considered adulterated and are barred from export to the United States. The certified establishment must notify the OV if a positive result for *Lm* or *Salmonella* is obtained from a product sample or if a positive result for *Lm*, *Listeria* species, or *Listeria*-like organisms is received for FCS samples, as the Prevention Department will not allow the export of these products to the United States.

The FSIS auditors reviewed the document requiring the establishment to develop and implement a microbiological testing program, *Protocollo analisi autocontrollo 2021 San Marino Salumi S.r.l.* The plan includes sampling and testing by the establishment of finished product for *Lm* and *Salmonella* and swabbing by the establishment of FCS during pre-operative and operational phases of production. The establishment collects swab samples at the pre-operational phase at the frequency of three swabs each quarter and, during the operational phase, the establishment collects five swabs (ranging from single swab to a composite sample of four swabs) each quarter. These swab samples are then analyzed for *Lm* or its indicator organism.

The samples collected under the official government testing program are analyzed at the microbiological section of the government owned and operated Public Health Laboratory. The Prevention Department requires the laboratory to employ the latest FSIS MLG methods for *Lm* (*FSIS MLG 8.11 2019*) and *Salmonella* (*FSIS MLG 4.10 2019*). Through interviews and document review, the FSIS auditors confirmed that the laboratory implements methods of analysis consistent with FSIS methodology for analyzing samples associated with RTE pork products intended for export to the United States.

The Prevention Department organizes and administers microbiological testing programs to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. There have not been any POE violations related to this component since the prior FSIS audit in 2019.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held remotely on June 2, 2021, with representatives from the Prevention Department. At this meeting, the FSIS auditors presented the preliminary outcome of the audit. An analysis of each component did not identify any deficiencies. Accordingly, the FSIS auditors concluded that the audit results confirm that the Prevention Department’s food safety inspection system governing pork destined for export to the United States continues to meet the established FSIS equivalence criteria.

Appendix: Foreign Country Response to the Draft Final Audit Report



U.O.C. SANITÀ PUBBLICA
Istituto per la Sicurezza Sociale

San Marino, 10 novembre 2021/2021 d.F.R
Prot. n. 5856 /DSP-V2 /2021

U.O.S. Sanità veterinaria e Igiene alimentare

Ill.ma

Dott.ssa Michelle Catlin, PhD
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Office of International Coordination

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of Foreign Agricultural Service
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U.S. Embassy
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Italy

Dear Ms Catlin,

I received your letter of last 14th September with which you sent us the draft of the final audit report following the ongoing remote audit of the San Marino meat inspection system from April to June 2, 2021.

The FSIS auditors concluded that the audit results confirm that the Prevention Department's food safety inspection system governing pork destined for export to the United States continues to meet the established FSIS equivalence criteria or that San Marino's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements and that the analysis of each component did not identify any deficiencies.

I specify that we have no comments to make regarding the final report.

However, we take this opportunity to highlight three aspects:

1. on page 1 of the report, the position of San Marino with APHIS is underlined: "The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes San Marino as free of African Swine Fever (ASF) and free of Foot-and-Mouth Disease (FMD) but with special restrictions. APHIS has also identified San Marino as affected with Classical Swine Fever (CSF) and Swine Vesicular Disease (SVD)."

It will be our goal to get in touch with APHIS to better define our position being the undersigned also the OIE Delegate for San Marino.

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2. I believe that it is fundamental to achieve the objective of guaranteeing increasingly effective controls with a view to improve action in the field of Food Safety, and that this success depends on the effectiveness of training activities.

The training actions we have undertaken have been structured and have met organically the needs and requirements of both the entrepreneur and the supervisory bodies, despite some difficulties, well known to you, mainly related to the resources that a micro-State can allocate to these activities.

Unfortunately this program has undergone a deceleration following the retirement of the Veterinary Supervisor dated July 2021; for its replacement we have issued a public competition according to our regulations which will take place by Christmas; moreover, in these days we are developing a new Official Control Plan that also takes into account our resources. It will be my responsibility to send you the draft of the new Plan as soon as it is ready.

3. With reference to what was declared in the final Report (page 7), it is intended to specify the following:

Dr. Raffaella Sapigni and TO Luca Berardi, are qualified to conduct internal audits accordingly to European standard UNI CEI EN ISO / IEC 17025, competence acquired since 2009 at the UNI - UNICHIM federated body.

Italian Accreditation Body ACCREDIA guidelines require that third party audits shall be conducted only by qualified/contracted ACCREDIA inspectors.

To ensure that the internal audit is conducted impartially and transparently without conflicts of interest, the Head of Laboratory has chosen to have internal audits conducted by qualified/contracted ACCREDIA inspectors.

Sincerely

Dr. Antonio Putti

Responsabile U.O.S. Sanità Veterinaria e Igiene Alimentare



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