FINAL REPORT OF AN AUDIT CONDUCTED IN

SAN MARINO

MARCH 4 THROUGH 8, 2019

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

August 1, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) from March 4 through 8, 2019. The purpose of the audit was to determine whether San Marino's food safety inspection system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. San Marino currently exports ready-to-eat (RTE) fully cooked - not shelf stable pork products.

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

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

GOVERNMENT SANITATION

- The CCA did not document verification of San Marino's requirements in *DGISAN 35665* for handwashing to prevent *Listeria monocytogenes (Lm)* in RTE establishments.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- The Central Competent Authority's (CCA's) inspection system failed to ensure compliance with HACCP requirements including:
  - 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 audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of San Marino's food safety inspection system from March 4 through 8, 2019. The audit began with an entrance meeting held on March 4, 2019, in San Marino during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – *Prevention Department (Dipartimento Prevenzione)*.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing processed pork 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 currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products
Fully Cooked - Not Shelf Stable	Ready-To-Eat (RTE) fully-cooked meat	Processed pork - all products eligible
Fully Cooked - Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Processed pork - all products eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes San Marino as free of Foot-and-Mouth Disease (with special restrictions) and free of African Swine Fever. APHIS has identified San Marino as affected with Classical Swine Fever and Swine Vesicular Disease.

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

Representatives from the CCA accompanied the FSIS auditor throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters and one local inspection office. The FSIS auditor evaluated the implementation of control systems in place 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 CCA has certified eligible to export to the United States. The establishment produces, and exports ready-to-eat (RTE), fully cooked-not shelf stable pork products to the United States.

During the establishment visits, the FSIS auditor paid particular attention to how industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed the CCA'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) Part 327.2.

Additionally, one government microbiological laboratory was audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits	**#**	**Locations**
Central Competent Authority	1	• *Prevention Department*, San Marino
Laboratory	1	• *Public Health Laboratory* (government microbiological), San Marino
Pork processing establishment	1	• Establishment 2L, San Marino Salumi s.r.l., San Marino

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*); 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 meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures.*

III. BACKGROUND

From January 1, 2016 to December 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 126,405 pounds of RTE pork products exported by San Marino to the United States. FSIS also performed re-inspection on 6,668 pounds at POE for additional types of inspection, including testing for the microbiological pathogens *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products, of which no products were rejected for issues related to public health. The previous FSIS audit in 2017 identified following findings:

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- The critical limit for critical control point (CCP) 1C was misidentified, as it was defined as the concentration of nitrite in the final product (<150 ppm) rather than the amount of nitrite added to the brine mixture (this was the point that was actually being measured, rather than the concentration in the final product).

- The frequencies at which ongoing verification procedures (i.e., direct observation of monitoring, review of records, and calibration of processing instruments) were not clearly defined in the establishment's HACCP plan. Additionally, the ongoing verification records did not clearly distinguish between direct observation of monitoring and review of records.

- The establishment elected to list *specific* corrective actions to be taken in response to deviations for each of the critical limits identified within its HACCP plan, rather than referencing the *general* requirements outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Part 417.3(a). However, the specific actions set forth did not include all four parts of the required corrective actions stated in the regulation.

The FSIS auditor determined that the CCA's corrective actions in response to the prior findings were not entirely effective, as the current audit identified some repetitive HACCP findings.

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

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

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

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

The national government of San Marino organizes and manages the meat inspection system. The CCA is the *Prevention Department* within the Institute for Social Security (*Istituto per la*

Sicurezza Sociale, ISS). Article 4 in Chapter II of *Delegated Decree n. 73/2012, Official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules,* explicitly identifies the *Prevention Department* as the San Marino competent authority. The *Prevention Department* is comprised of five organizational units: Labor Medicine and Hygiene; Environmental Protection; Workplace Safety; Veterinary Health and Food Hygiene (VHFH); and, the Public Health Laboratory. The VHFH is the unit exclusively responsible for the inspection of meat products. There have been no significant organizational changes within the *Prevention Department* since the last FSIS audit.

The CCA 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 n. 85 (1992)*. The CCA's *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*, includes instructions for government inspection personnel to verify the certified establishment complies with FSIS requirements in 9 CFR Parts 416, 417, 430, and all other relevant regulations. Annex A of *Prot. No. 3169/DPS-V2 (2017)*, *Manual for the performance of official controls in the assessment of compliance with US regulations*, hereafter "*Official Controls Manual*", contains specific government procedures to ensure compliance with FSIS requirements.

In the event of noncompliance, the Official Veterinarian is required to document the findings and verify adequate corrective actions. For repetitive noncompliance, the CCA has provisions to delist eligibility of the establishment to export to the United States. San Marino *Law n. 85/1992, Hygiene in Production, Storage, Transportation, Sale and Supply of Food and Beverages, Article 12, Sanctions*, provides the CCA with enforcement authority for sanctions due to the failure to comply with rules established by the CCA, including suspension of operations, issuance of administrative fines, seizure of product, and penalties associated with criminal law offenses where appropriate.

The FSIS auditor verified that in cases where the Official Veterinarian identified noncompliance, they prepared a written noncompliance record, and conducted the appropriate follow-up to ensure the issues were resolved prior to closing out the record. The CCA has not implemented any enforcement actions since the last FSIS audit.

San Marino *Law n. 85/1992*, Article 6 defines adulterated food and states that it is prohibited to possess, sell, use, and administer adulterated foods. Article 14 of *Delegated Decree n. 68/2012* states that food labels should not be misleading to consumers. The CCA's *Protocol 0512UOS (2016)* provides a set of comprehensive recall procedures to be followed by both industry and inspection personnel in the event adulterated products are produced. These procedures include requirements for the maintenance of records sufficient to conduct trace-back activities, as well as specific instructions to notify the United States Embassy in Rome and FSIS management of any affected product that would be in route to the United States. There have been no pork product recalls for any market since the last FSIS audit.

The Official Veterinarians assigned to the establishment are responsible for export certification. All export certification items including stamps are located in the secure government office at the establishment. The Official Veterinarian assigns a unique export certification number to each export certificate. The Official Veterinarian conducts a pre-shipment review that includes all associated traceability documents, including verification of the raw meat source used to produce products, and food safety records for each lot prior to applying the official stamp and signature on the export certificate. The Official Veterinarian review includes ensuring that all products have tested negative for pathogens whether through establishment or official sampling programs prior to signing an export certificate.

The CCA has export certification procedures that include traceability throughout the production process to ensure meat products certified for export to the United States meet all requirements. The FSIS auditor verified in the audited establishment that the official inspection security of controls was in place associated with the export process including certification records and official seals.

The CCA ensures that source meat products used in process operations originate from certified establishments in eligible countries. San Marino is not eligible to slaughter and export raw pork to the United States. The certified establishment in San Marino sources raw pork meat from Italy, Denmark, or other European Union (EU) Member States that are eligible to export to the United States. The certified establishment must notify the VHFH one week in advance of the intent to import fresh meat for use in preparing product for export to the United States. At the arrival of fresh meat, the Official Veterinarian verifies the health certificates of origin and official seals on the truck. Additionally, the Official Veterinarian verifies controls including the temperature of the transport truck, hygiene, and proper marking of meat.

The FSIS auditor noted that the Official Veterinarian verifies that each shipment of source meat used for the production of products produced for export to the Unites States originates only from establishments certified to export to the United States by utilizing the FSIS website listing eligible establishments by country. This was verifiable onsite by cross-referencing the export certificates with the bills of lading and additional certifications (e.g., health certificates, transfer certificates) that accompany each shipment of source materials. The FSIS auditor verified that the Official Veterinarian maintained the pertinent documents for each production lot intended for export to the United States.

The CCA maintains a single standard of laws, regulations, and procedures applicable to the establishments certified to export to the United States. San Marino has implemented specific hygiene requirements in Delegated Decrees based on European Commission regulations to allow trade within the European Union. The CCA maintains the authority and responsibility to certify and de-certify establishments in accordance with Article 9 of *Law n. 85/1992*. Requirements for approval of food business establishments are contained in Article 4, *Registration and Approval of Establishments*, of *Delegated Decree n. 71/2012*.

The Veterinary Supervisor must conduct an on-site verification visit to evaluate compliance with United States requirements prior to the CCA designating an establishment eligible to export to the United States. In addition, the CCA requires companies intending to export products to the

United States to submit a request to the VHFH on an annual basis per *Prot. n. 7969 /DSP V2/2017*, *Compliance with US Export Purposes*. Currently, there is only one establishment certified eligible to export processed pork products to the United States.

The CCA communicates requirements to official inspection personnel via email or the Internet. Additionally, the CCA and the *Public Health Laboratory* share the same location, so there is free flow of communication between the two entities. The CCA evaluates any new information received from FSIS and distributes information through the supervisory chain of command and to the Official Veterinarians. The FSIS auditor verified that the CCA maintains mechanisms to disseminate any new information to inspection officials and the establishment in a timely manner.

The CCA is comprised of a staff of five government veterinarians in the VHFH office. The Official Veterinarians assigned to the certified establishment and the Veterinary Supervisor are employees of the national government. San Marino's *Law n. 41/1972,* Article 3 describes the principles to ensure the relationship between the public administration and employee guarantees services in the interest of the republic. Article 53 of the same law explicitly describes salaries paid by the State Treasury. The ISS directly pays the salaries of the government personnel.

The CCA's *Prot. n. 1125/DSP-V2/2016*, Section 7, explicitly requires that staff involved in official controls be free from any conflict of interest and must comply with the behaviors marked by independence, impartiality, integrity, transparency, and confidentiality. The FSIS auditor reviewed documentation demonstrating that the government of San Marino employs and directly pays the salaries of the official inspection personnel.

The CCA specifies requirements for once per shift inspection coverage in *Prot. n. 3169/DPS-V2/2017* and *Prot. n. 8405/DSP V2/2017* based on 9 CFR Part 307.4 and FSIS requirements. The Official Veterinarian conducts inspection activities during each production shift for products intended for export to the United States and documents inspection presence on official records (*Registro Presenze San Marino Salumi)*. The FSIS auditor cross-referenced the inspection presence records and establishment production records to verify that the CCA ensured inspection at least once per shift whenever production for the United States occurred.

The CCA is responsible for ensuring that government inspection personnel have the appropriate educational credentials, experience, and training to carry out their inspection responsibilities. As noted, the VHFH is comprised of veterinarians and the minimum educational requirement for Official Veterinarians is five years of professional veterinary studies at the university level. San Marino *Law n. 107/2009* defines requirements governing the competitive recruitment and selection standards for civil service employment, including examinations and probationary periods following selection.

The CCA provides courses, seminars, and conferences to address requirements for meat products intended for export to the United States. *Prot. n. 1125/DSP-V2/2016, Plan of Official Controls on Food Safety*, provides that the competent authorities ensure that all staff performing official controls receive, for their area of competence, appropriate training in relation to the specific activity that will enable them to competently perform their duties in accordance with *Delegated*

Decree n. 73/2012. The FSIS auditor verified that the CCA has continued to provide training opportunities for the official inspection personnel.

In 2017, the Official Veterinarian and Veterinary Supervisor attended multiple training courses organized by Italy's Ministry of Health that included classroom sessions, as well as, on-site visits to certified establishments. In May 2018, the inspection personnel attended training provided by the Italian CCA covering sampling and verification methods for HACCP requirements. In addition, since the last audit, training has included two courses on export requirements for third countries and one course on sampling food. The FSIS auditor verified that the supervisor and Official Veterinarian assigned to the audited establishment had completed all of these training sessions.

San Marino's *Public Health Laboratory* (*Laboratorio di Sanità Pubblica*) provides technical laboratory support for microbiological testing and conducts official analyses for the purpose of export to the United States. *Delegated Decree n. 73/2012, Article 11*, requires the CCA to designate laboratories that may conduct analyses of official samples. The competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the European standards including the International Organization for Standardization (ISO) 17025*, General Requirements for the Competence of Testing and Calibration Laboratories*.

The CCA relies on the accrediting organization, *Accredia* (*L'Ente Italiano di Accreditamento*), to conduct laboratory accreditation audits and to assess compliance with ISO 17025 standards for the *Public Health Laboratory* of San Marino. The FSIS auditor verified that *Accredia* certified that the laboratory met ISO 17025 requirements in February 2015.

The government *Public Health Laboratory* operates under a quality manual and procedures developed under the ISO 17025 accreditation process. In addition, the CCA has developed *PGL 03 Rev.2*, *Laboratory Management Procedures*, that provides detailed instructions for sample selection, transport, receipt, and analysis using current FSIS Microbiology Laboratory Guidebook (MLG) methods, reporting of results, and follow-up testing. The *Public Health Laboratory* participates in annual inter-laboratory proficiency tests organized by the Italian Veterinary Public Health Institute (*Istituti Zooprofilattici Sperimentali,* IZS) laboratory in Teramo, the Italian National Reference Laboratory. The FSIS auditor did not identify any concerns.

The FSIS auditor verified that the CCA'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 of six equivalence components that the FSIS auditor 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 Veterinary Supervisor conducts periodic supervisory visits to ensure establishment compliance with requirements for eligibility to export to the United States according to procedures identified in *Prot. n. 3169/DPS-V2/2017* and the *Official Controls Manual*. The supervisory visit consists of reviewing establishment compliance with requirements and evaluating the activities carried out by the Official Veterinarian in accordance with the manual. The scope of the supervisory visit includes the export certification process and official controls over establishment construction, facilities, equipment, sanitation standard operating procedures (sanitation SOPs), HACCP, and other programs in accordance with FSIS regulations.

Additionally, the periodic supervisory visit verifies the completeness and effectiveness of routine controls by the Official Veterinarian. The supervisory visit frequency is a minimum of four times per year but may be increased. The FSIS auditor confirmed supervisory visits are being conducted a minimum of four times per year and include performance assessment of the Official Veterinarian. However, similar to the 2017 FSIS audit, the Veterinary Supervisor did not accurately assess compliance with some HACCP requirements.

The CCA's *Official Controls Manual*, *Section 5.3 HACCP*, provides detailed verification activities related to evaluating compliance with HACCP requirements. However, the FSIS auditor identified findings during the current and previous audits for failure to meet the requirements of a HACCP plan. The CCA's implementation of the revised verification procedures in 2017 was not adequate to ensure resolution of all the previous audit findings nor prevent the recurrence of additional HACCP findings during the current audit.

The CCA requires that establishments producing product intended for export to the United States provide complete separation of product from that intended for other countries, including the use of dedicated workdays for the exclusive production for the respective markets. *Prot. n. 8405/DSP V2/2017*, *Compliance for US Export*, requires the Official Veterinarian to ensure production for export to the United States takes place separately from any preparation or production intended for the internal market.

Protocol No 2407/2009 requires production of products intended for the United States to occur on exclusive work days or distinctly separate from production for the European Union market. In addition, this document requires the certified establishment to notify the VHFH at least 24 hours prior to the arrival of source meat for products intended for export to the United States.

The FSIS auditor confirmed that the establishment provides adequate prior notification of planned production to the Official Veterinarian to ensure official inspection coverage. Furthermore, the FSIS auditor verified the identification and segregation of products and operations to ensure separation of products produced for export from those for the domestic market. No concerns arose during the audit concerning planned production or the separation of products.

San Marino exports fully cooked, not shelf stable RTE pork products to the United States that must comply with 9 CFR Part 94 in order to meet APHIS requirements. San Marino is not eligible to conduct slaughter operations or process raw pork for export to the United States. San Marino sources raw pork used in the processing of RTE products for export to the United States from certified establishments in eligible countries, currently Denmark and Italy. The FSIS auditor verified at the audited establishment that the Official Veterinarians ensure compliance with APHIS requirements prior to export certification including veterinary certification of received pork meat, deboning, and heat treatment to ensure an internal temperature of 69 °C.

San Marino requires that 9 CFR Part 416 and all other provisions are met in each certified establishment. The *Official Controls Manual*, Section 5.1.9 identifies the requirements of 9 CFR Part 416.3(c) and the verification activities to ensure control over inedible material. Additionally, Chapter VI (*Food Waste*) and Chapter IX (*Requirements Applicable to Food Products*) of Annex II in *Delegated Decree n. 70/2012, Food Products Hygiene*, address San Marino's requirements for food business operators concerning the identification, handling, and disposal of food waste, non-edible byproducts, and other waste products. The food business operator must remove food waste and non-edible products as soon as possible and deposit waste into lockable containers. All waste must be disposed of in an environmentally sound and hygienic manner. The FSIS auditor verified the use of a locked container clearly identified as inedible for the disposal of inedible products during production.

The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. However, as discussed in the Government HACCP System component section, the supervisory visits were not effective in ensuring resolution of the previous FSIS audit findings.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

San Marino's inspection system requires establishments eligible to export to the United States meet the sanitation requirements in 9 CFR Part 416 and all other provisions. Additionally, *Delegated Decree n. 70/2012*, *Food Products Hygiene*, requires that food business operators ensure that the preparation, processing, manufacturing, packaging, storage, and transport of food products are carried out in a hygienic manner and *Annex II*, *General Hygiene Requirements*, describes sanitation requirements analogous to the FSIS Sanitation Performance Standard requirements in 9 CFR Part 416.

San Marino requires the development of sanitation SOPs as identified in *Decree n. 32/2005*, *Sanitary Regulations for Food Products*, where Article 4 outlines requirements analogous to 9 CFR Part 416.11 to 416.17. Additionally, Article 5 of *Delegated Decree n. 70/2012*, *Food Products Hygiene*, requires food business operators to develop sanitation SOPs in implementing the requirements contained in *Decree n. 32/2005* and subsequent amendments. *Delegated*

Decree n. 70/2012, *Article 13, Sanctions*, further provides for enforcement actions in response to the failure to comply with sanitation requirements. Potential enforcement actions include monetary fines and revocation of authorizations, and suspension of plant activities in the event of repetitive noncompliance cases as established by *Law n. 85/1992*, Article 12.

The CCA has identified specific sanitation requirements in establishments producing post-lethality exposed (PLE) RTE product in *DGISAN 35655-P (9/16/2015)*. Establishments are required to verify sanitation by testing food contact surfaces for *Lm* or indicator organisms and develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, sanitation SOP, or other prerequisite program. *DGISAN 35655-P (9/16/2015)* contains requirements for the establishment to implement specific sanitation measures, including employee hygiene measures such as washing and sanitizing hands prior to entering PLE production areas and the use of disposable gloves when handling PLE products. Lastly, management is required to monitor the specific hygiene requirements. The FSIS auditor identified the following finding:

- The CCA did not document verification of San Marino's requirements in *DGISAN 35665* for handwashing to prevent *Listeria monocytogenes (Lm)* in RTE establishments.

During the audit, the FSIS auditor observed that the audit team, including establishment management, did not wash and sanitize hands when entering the PLE production area. Additionally, through interviews, the FSIS auditor determined that establishment management did not have specific handwashing and hand sanitation requirements in place; employees were expected to wash and sanitize their hands prior to leaving the locker room. Further, the establishment had implemented the use of reusable gloves in the PLE production process, again contrary to the CCA's requirements in *DGISAN 35665-P (9/16/2015)*. Therefore, the establishment has failed to design and implement the operational sanitation SOP or other prerequisite procedures to ensure compliance with the sanitation requirements outlined in *DGISAN 35665-P (9/16/2015)*.

The CCA's *Official Controls Manual* describes the regulatory requirements and verification activities performed by government inspection personnel to ensure compliance with sanitation requirements. The Official Veterinarian must verify that the establishment's sanitation programs and operations are sufficient to prevent adulteration of products. Pre-operational sanitation verification is conducted a minimum of once monthly while daily operational sanitation verification is conducted each shift. The CCA requires official inspection personnel to document noncompliance with requirements and requires the establishment to implement adequate corrective actions. The FSIS auditor reviewed noncompliance reports and supervisory visit reports and verified records demonstrating the establishment's corrective actions and verification by the official inspection personnel indicated that the corrective actions were implemented and effective.

The FSIS auditor verified the adequacy of official verification and inspection activities related to sanitation programs at the establishment certified to export to the United States by observing official inspection personnel assess the implementation of the establishment's sanitation procedures. The FSIS auditor assessed the adequacy of pre-operational sanitation by observing

the Official Veterinarian conduct pre-operational verification of the audited establishment's sanitation program. The Official Veterinarian conducted this activity in accordance with the established procedures including an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils. The FSIS auditor also reviewed inspection records and assessed the overall sanitary conditions of production areas and storage rooms.

The CCA's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component. However, the FSIS auditor identified sanitation procedures in PLE areas inconsistent with the CCA's requirements.

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

The fourth of six equivalence components that the FSIS auditor 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 FSIS auditor verified that the CCA requires establishments to design, implement, and maintain HACCP systems in accordance with United States requirements. San Marino requires the development of a HACCP system as identified in *Decree n. 32/2005*, *Hygiene Regulations for Food Products*. Article 5, HACCP, defines requirements analogous to 9 CFR Part 417. Per Article 9, failure to comply with the HACCP requirements results in administrative sanctions and repeat offenders may be subject to the suspension of the business activity or other sanctions contained in *Law n. 85/1992*, Article 12. Additionally, Articles 1 and 5 of *Delegated Decree n. 70/2012, Food Products Hygiene,* requires food business operators to develop HACCP programs. Chapter XII in Annex II of this decree requires HACCP principles training of food business operators and food handlers. Lastly, *Prot. No 3169/2017*, states that establishments approved to export to the United States must meet the requirements of 9 CFR Part 417.

The CCA's *Official Controls Manual* provides verification instructions to ensure compliance with HACCP requirements. The official inspection team conducts daily verification activities for HACCP requirements through direct observation and hands-on activities as well as review of records. In addition, inspection personnel perform a hazard analysis verification activity to ensure establishments consider and address the relevant hazards.

At the audited establishment that produces RTE products, the FSIS auditor reviewed the HACCP system with a special emphasis on lethality for *Salmonella* and other relevant pathogens in accordance with *DGISAN 35655-P (9/16/2015).* The CCA requires that each RTE establishment have validated support for *Salmonella* lethality ensuring at least a 6.5-$\log_{10}$ reduction in cooked pork products using time and temperature parameters in FSIS Appendix A. The establishment must also address stabilization using options and parameters in FSIS Appendix B. The FSIS auditor verified that the establishment uses FSIS Appendices A and B to ensure lethality and stabilization requirements.

The FSIS auditor verified that the audited establishment had developed a flow chart and conducted a hazard analysis for expected hazards. For specific hazards that are reasonably likely

to occur, the establishment has instituted CCPs described in their HACCP plans. The FSIS auditor also verified that official inspection personnel conduct daily HACCP verification activities during production for export to the United States. The FSIS auditor identified the following findings:

- The CCA's inspection system failed to ensure compliance with HACCP requirements including:
  - 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 CCP monitoring records did not include actual values obtained at the time of monitoring.

The findings did not pose a direct threat to the safety of the RTE products because the establishment had supported and implemented HACCP system controls for lethality and stabilization, based on FSIS Appendices A and B, respectively. While the establishment conducts verification activities, the establishment has not based those activities on the types of ongoing verification activities required in a HACCP plan. The establishment has an extended history of meeting the critical parameters during production. However, in the absence of a properly designed HACCP plan, the establishment cannot ensure proper implementation and verification of the effectiveness of the plan.

The FSIS auditor verified that the CCA requires establishments certified to export to the United States to develop and implement HACCP systems. However, the 2017 FSIS audit identified the same, or similar, HACCP findings and the CCA's response to the prior audit findings was not adequate to ensure resolution of the findings. The FSIS auditor determined that knowledge and training regarding the requirements for HACCP plans and HACCP recordkeeping requirements are deficient.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

In order to meet the requirements of a chemical residue testing program, San Marino relies on third countries' national residue monitoring programs, as the country receives its raw pork product from slaughter and processing establishments certified to export to the United States from equivalent countries. At the time of the audit, the establishment had sourced raw pork from Italy and Denmark. The CCA relies on certification of products by the Official Veterinarians in the source countries. In addition, Europe's *Rapid Alert System for Food and Feed (RASFF)* provides email alerts to any importing country whenever a country recalls product or identifies

product that exceeds maximum residue limits (MRLs). Adulterated product, including that exceeding MRLs, cannot enter San Marino.

The FSIS audits of the meat inspection systems for both Italy (2018) and Denmark (2018) did not identify significant findings related to the control of chemical residues. Furthermore, there have not been any FSIS POE violations for chemical residues from Italy or Denmark.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The CCA's *Prot. n. 8405/2017*, *Compliance for US Export*, states that the measures identified in the Italian Ministry of Health circular *DGISAN 35665-P (9/16/2015)* are adopted in San Marino. The circular describes RTE requirements, official verification procedures, and sampling procedures, highlighting the critical importance of sanitation measures, especially in PLE processing areas. Specifically, the requirements dictate zero tolerance for *Lm* and *Salmonella* in RTE products and require the same controls for *Lm* as 9 CFR Part 430.

The CCA's official sampling and testing programs for *Salmonella* and *Lm* are also defined in *DGISAN 35665-P (9/16/2015).* The purpose of the sampling programs is to verify the effectiveness of the establishment's sanitation programs and control measures to prevent *Lm* and *Salmonella* in RTE pork products destined for export to the United States. The CCA implements official verification sampling including risk-based RTE product sampling as well as non-risk-based sampling for all RTE products, whether PLE or not. Lastly, the CCA has implemented an official verification risk-based *Lm* (RLm) annual sampling program that includes sampling of 10 food contact surfaces (FCS), 3 indirect food contact surfaces (INFCS), 2 non-food contact surfaces (NFCS), and 5 finished RTE products which are analyzed for *Lm* and *Salmonella.* The Official Veterinarians conduct all official sampling using the sponge method on surfaces focusing on operational timeframes but including pre-operational samples and collection of finished RTE products in final packaging. Official inspection personnel transport and deliver the samples to the laboratory. The CCA requires that all sampled RTE products be held pending analytical results. The FSIS auditor reviewed results since the last FSIS audit and all official sample results have been negative for *Lm* and *Salmonella*.

The FSIS auditor verified that the establishment has designed, and implemented, a written pre-requisite program to meet the requirements of a *Listeria* program as specified in *DGISAN 35665-P (9/16/2015)*. The establishment conducts sampling of FCS, NFCS, and RTE product. The FSIS auditor verified that the establishment conducted expected corrective actions in response to the finding of *Listeria spp.* in the PLE processing area, following the procedures required in *DGISAN 35665-P (9/16/2015)*. In addition, the official inspection team conducted official verification sampling designed to ensure the establishment's corrective actions were effective. The corrective actions were sufficient to demonstrate that the establishment restored sanitary

conditions in the PLE processing area. The laboratory confirmed the isolates were negative for *Lm,* but in accordance with the CCA's requirements, the establishment could not export product to the United States during this timeframe.

San Marino utilizes the *Public Health Laboratory* to analyze official verification samples collected from the certified establishment. The laboratory uses the official FSIS MLG 8.10 method for *Lm* and *Listeria spp.* on RTE products and on surfaces and the FSIS MLG 4.09 method for *Salmonella* spp. on RTE products produced for export to the United States. The CCA requires the official laboratory to adhere to the latest FSIS MLG methods.

The FSIS auditor verified that the *Public Health Laboratory* had implemented the FSIS MLG methods updated in January 2019 but was awaiting the results from proficiency testing prior to completely adopting the revised methods. Additionally, the CCA requires certified establishments to apply the FSIS test methods or methods that are at least equivalent and validated in a laboratory that demonstrates accreditation of the methods in accordance with ISO 17025. The CCA's *PGL 03 Rev.2/2017, Sampling Cooked Hams Destined for United States Export,* provides specific requirements regarding sample collection, integrity, chain of custody, and testing methods. The laboratory analyzes samples once and does not perform any re-testing of samples.

During the visit to the government's *Public Health Laboratory*, the FSIS auditor reviewed analyst qualifications, sample receipt, timely analysis, analytical methods and controls, recording and reporting of results, calibration of equipment, internal audits, traceability, inter-laboratory proficiency testing, and sample result reporting. The FSIS auditor observed the sample receipt process and concluded that chain of custody, sample transport controls, and documentation ensured the integrity of the sample and process. The FSIS auditor also observed the laboratory technician sampling a RTE ham using aseptic technique outlined in *PGL 03 Rev.2/2017.* A review of inter-laboratory proficiency tests identified 100 percent accuracy in the most recent round of analyses. The FSIS auditor observed the process for Section Coordinator review of analyst results and validation of results by the head of the laboratory. The laboratory issues test results through the laboratory database and transmits results via email to the VHFH office as well as the Official Veterinarian. In addition, the system documents acknowledgement that the recipients received the results.

There have not been any POE violations related to this component since the last FSIS audit. The CCA 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. The CCA's meat inspection system continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

The FSIS auditor held an exit meeting with the *Prevention Department* on March 8, 2019, in San Marino, the Republic of San Marino. The FSIS auditor presented the preliminary findings from the audit during this meeting.

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

GOVERNMENT SANITATION

- The CCA did not document verification of San Marino's requirements in *DGISAN 35665* for handwashing to prevent *Listeria monocytogenes (Lm)* in RTE establishments.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- The CCA's inspection system failed to ensure compliance with HACCP requirements including:
  - 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 CCP monitoring records did not include actual values obtained at the time of monitoring.

The audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
San Marino Salumi S.r.I. . Strada del Lavoro 45-47892 Gualdicciolo San Marino	03/05/2019	SM CE 2L	San Marino
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

15/51. The establishment's HACCP plans do not include all required ongoing verification procedures and frequencies. For CCP C1 the HACCP plan does not identify a frequency for direct observation of monitoring and does not identify the calibration procedures and frequency. For CCP B1 the HACCP plan does not identify the review of records procedure and frequency; the direct observation of monitoring procedure and frequency; nor the calibration procedure and frequency.

22/51. The establishment's monitoring records for CCP C1 do not include actual values obtained at the time of monitoring. The establishment's verification records for CCP C1 do not include the type of verification being performed and do not include the results of the verification activity.

58/51. The establishment produces post-lethality exposed ready-to-eat (RTE) products and is controlling the hazard of *Listeria monocytogenes* through sanitation only, Alternative 3. However, the establishment has failed to include operational Sanitation SOP or other prerequisite procedures to ensure proper employee hygiene by requiring employees to wash and sanitize hands prior to entering RTE production rooms and prior to donning re-usable gloves in the "de-molding" and packaging room, a room where post-lethality exposed products are handled. This is a failure to meet the requirements in DGISAN 35665.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2019

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

DIPARTIMENTO PREVENZIONE
Istituto per la Sicurezza Sociale

San Marino, 04/07/2019/1718 d.F.R
Prot. n. 4924 /DSP-V2/2019

DIREZIONE

Michelle Catlin
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Indipendence Avenue, SW.
20250Washington, D.C. U.S.A.

Thank you for your letter dated 4 June 2019 in which you provided the Food Safety and Inspection Service (FSIS) Draft Final Report of the audit of the San Marino Export Meat Inspection System conducted by FSIS from 4 March 2019 through 8 March 2019. We appreciate FSIS for the opportunity to comment on the Draft of the Final Report. During the auditing phases, the company immediately recognized the problems related to the HACCP and immediately proceeded to carry out the modifications necessary to adapt to the inspector's requests.

After the exit meeting, the CCA has addressed the preliminary finding and San Marino Salumi immediately made the changes noted performing a reassesment of the HACCP Plan and CCP logs.

Just received the final draft report, CCA sent to the company an official note dated 17/06/2019 prot. 4499 DSP V-2/2019 to officially indicate the corrective measures to be taken.

COMMENTS FOR FSIS CONSIDERATION:

VI COMPONENT THREE: GOVERNMENT SANITATION: The FSIS auditor determined that establishment management did not have specific handwashing and hand sanitation requirements in place.
CAA Response We believe we have adapted to the standards in question through the **Official notification** sent to San Marino Salumi on 17/06/2019 prot.4499 DSP V-2/2019 Non-disposable gloves are used for safety reasons just to take hot molds.
CAA Request None

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DIPARTIMENTO PREVENZIONE
Istituto per la Sicurezza Sociale

VI COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT(HACCP) SYSTEM The CCA's inspection system failed to ensure compliance with HACCP requirements including: o 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 CCP monitoring records did not include actual values obtained at the time of monitoring .
CAA Response The report is accurately assesses the exact correspondence with the 9CFR417. The company has been producing food since thirty years on follow HACCP system; in fact the system according to Regulation EC 852 and Regulation EC 853 is in line with European standards. The real problem is the exact correspondence between the European system. of self-control and the American self-control system. We believe we have adapted to the standards in question through the **Official notification** sent to San Marino Salumi on 17/06/2019 prot. 4499 DSP V-2/2019
CAA Request None

We hope these comments fulfil your requirements. Please do not hesitate to contact us if you need further information or clarification.

Direttore Dipartimento Prevenzione

Dr. Andrea Gualtieri

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