



United States Department of Agriculture

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Food Safety and  
Inspection Service

JUL 20 2015

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

Dr. Maurizio Berardi  
Chief Veterinary Officer  
Veterinary Services  
Istituto Per La Salute Pubblica  
Via La Toscana, 3  
47893 Borgo Maggiore  
Republic of San Marino

Dear Dr. Berardi:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of San Marino's meat inspection system from July 21 through July 25, 2014. 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 technical questions regarding the proposed FSIS audit, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
SAN MARINO

July 21 – 25, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING  
THE PRODUCTION OF MEAT  
PRODUCTS INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

July 20, 2015  
Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) on July 21 through July 25, 2014. The audit was to determine whether San Marino's food safety inspection system governing the production of meat remains equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. San Marino is eligible to export processed pork products to the United States.

The audit focused on six main system equivalence components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. In addition, the auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the November 2008 FSIS audit findings had been implemented.

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters, a processing establishment, and one government laboratory. These audit locations were selected to verify that the national system of inspection, verification, and enforcement were being implemented as required to maintain equivalence.

The 2014 audit results indicate that the CCA's food safety inspection system is performing at an overall average level meeting the core criteria for all six equivalence components. The FSIS auditor did not identify any concerns in five equivalence components. However, FSIS identified operational (or procedural) weaknesses related to the Sanitation component, which are described in that component of the report.

During the exit meeting on July 25, 2014, the CCA noted that it has already begun to address the audit observations by implementing immediate corrective actions for the short-term and long-term prevention of recurrence. FSIS will evaluate any information provided by the CCA including the submission of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions.

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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 equivalence verification audit of the San Marino's meat inspection system on July 21 – July 25, 2014. San Marino is eligible to export processed pork products to the United States.

Between October 1, 2012 and July 31, 2014, San Marino has exported 5,966 pounds of fully cooked not shelf stable pork products. Of this volume, 3,719 pounds of the product was re-inspected at the United States Port-of-Entry (POE). No product imported from San Marino was rejected or refused entry.

This audit was conducted pursuant to the specific provisions of the United States laws (United States Code, U.S.C.) and regulations (Code of Federal Regulations, CFR), in particular:

- Federal Meat Inspection Act (21 U.S.C. 601 et seq.), and
- Federal Meat Inspection Regulations (9 CFR Parts 301 to end).

Although San Marino is a non-European Union (EU) country, the European Commission (EC) and San Marino jointly laid the foundation of the EC-SM Cooperation Committee of 28 June 1994 on Community veterinary regulations to be adopted by the San Marino. San Marino applies the standards found in the following EU regulations pertaining to food of animal origin:

EU Regulation:

- EC Regulation 852/2004,
- EC Regulation 853/2004,
- EC Regulation 854/2004,
- EC Directive 96/22/EC,
- EC Directive 96/23/EC,
- EC Directive 2004/41/EC, and
- EC Directive 2073/2005.

National Legislation:

- Republic of San Marino's Decree n. 32 of 09/03/2005 (amended),
- Republic of San Marino's Decree n. 70 of 29/06/2012, and
- Law of 29 October 1992, n. 85.

The audit standards applied during this audit included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process.

## **II. AUDIT GOAL AND OBJECTIVES**

FSIS' overall goal for the audit was to verify that San Marino's food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on six equivalence components to determine whether each component continues to be equivalent to that of the United States: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

During the audit of 2008, the one establishment in San Marino that was eligible to export to the United States was audited. As a result of the audit, the establishment was issued a Notice of Intent to Delist (NOID) by the CCA. The 2008 audit raised concerns in HACCP, Sanitation, and Microbiological components. During the current audit, the FSIS auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the November 2008 FSIS audit had been implemented. In FY2014, the one United States-certified establishment that is eligible to export to the United States was audited.

### **III. AUDIT METHODOLOGY**

FSIS utilized its four-phase process to conduct this equivalence verification audit-plan, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase is document and data review, including analysis of previous audit findings and other available information. Therefore, prior to conducting the July 2014 on-site audit, FSIS examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and other data collected since the last FSIS audit in 2008. In addition, the FSIS auditor reviewed information obtained directly from the CCA, through the Self-Reporting Tool (SRT), outlining the structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit.

The second phase is the on-site audit or execution phase. FSIS conducted this on-site audit to verify the CCA's oversight activities as they relate to each equivalence component. The auditor gathered data on all six components through document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the audit by representatives from the Department of Prevention (DP) (i.e., the CCA).

Management, supervision, and administrative functions were reviewed at the CCA headquarters and at one pork processing plant eligible to export to the United States to determine whether the national system of inspection, verification, and enforcement was being implemented as required to maintain equivalence. During the establishment visit, the auditor paid particular attention to the extent to which the government and industry interact to control hazards and prevent deficiencies that may threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9, Code of Federal Regulations (CFR), 327.2.

The FSIS auditor assessed the CCA's oversight activities for microbiology laboratory, including a review of the laboratory audit report for the audit conducted on behalf of the CCA and laboratory-related data compiled for a period of the last six months and through on-site interviews with inspection personnel. The auditor assessment also included an on-site audit of a government laboratory "Laboratorio di Sanità Pubblica" which was conducting microbiological analytical testing on official samples.

The third phase is an evaluation of all data collected on-site to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents.

The final phase is a feedback phase that begins with providing the CCA a draft audit report with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report and develops an action plan to address any issues raised by the audit.

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)**

The first of the six equivalence components reviewed was Government Oversight. The FSIS import eligibility requirements state that an equivalent foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States meat inspection system. The evaluation of this component included a review of documentation submitted by the CCA as support for the responses and corrective actions, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and in the audited establishment.

San Marino is a small republic situated on the Italian Peninsula on the northeastern side of the Apennine Mountains. Its geographical periphery is surrounded by Italy. San Marino is a non-EU country. The European Commission (EC) and San Marino jointly agreed to form an EC-San Marino Cooperation Committee on 28 June 1994. Under the term of the cooperation, San Marino applies the standards found in EU regulations pertaining to food of animal origin. As such, San Marino has implemented EC 178, EC 854, EC 882, and other EU regulation relevant to product of animal origin. The United States requirements not covered in the EU regulations are implemented through specific governmental issuances without prejudice to EU regulations.

The inspection system in San Marino can be traced back to a broad complex organization known as "Institute of Social Security" a public health and security body in the state. Since the last FSIS audit of San Marino in 2008, the institute has undergone reorganization under the provisions of executive decree of January 11, 2010, n. 1. However, the auditor noted that, no organizational changes at the CCA level or in the manner the inspection system operates changed. The Secretary of State for Public Health, who is supported by the General Manager and an Executive Committee (GMEC), heads the institute. The GMEC is charged with overseeing three departments within the administration of the institute; namely, the Department of Preventions, Social Sanitary and Mental Health and the Department of Hospital. FSIS recognizes Department of Prevention as the CCA for San Marino's meat inspection system and communicates with them on all import related matters.

The Department of Preventions is divided into four programs: Public Health Laboratory, Medicine and Health of Workers, Industrial Safety, and Protection of the Environment and Veterinary Health and Food Hygiene (VHFH). Within the VHFH is a directorate, which oversees three important veterinary service programs; namely, the Urban Hygiene, Animal Health, and Food Hygiene. The Official Veterinarian (OV) assigned to the United States-eligible establishment reports to the Food Hygiene component of the VHFH.

The VHFH mission includes the following:

- Prevention of zoonosis and prevention of animal diseases, diagnosis and treatment of diseases of breeding animals,

- Hygiene of food for animal use and protection of animal welfare, and
- Food hygiene control to protect the health of consumers.

The FSIS auditor reviewed the Legge (Law) 31 July 2009 n.107 which provides regulations governing the recruitment standards in civil service employment in San Marino. The law establishes the general and the vacancy specific procedures a potential applicant needs to meet in order to be selected for a position in the government-wide job vacancies system. The Title III of the aforementioned law establishes procedures on filling a career position with a potential for promotion within an agency. To be assigned as an official veterinarian in a meat slaughter or processing establishment the CCA ensures that the assigned veterinarian must meet EU-criteria established for the recruitment of veterinarians. These criteria on professional qualification for veterinarians to work in meat/poultry inspection are outlined as in chapter IV (point 1-7). The auditor reviewed the procedures of appointment of the official veterinarian assigned to the United States-eligible establishment and determined that the CCA follows the applicable national and EU regulations in the recruitment procedure.

San Marino has an on-going training program and ensures that the inspection staff across the inspection system receives appropriate training. The following documents were evaluated:

- Personnel training update,
- Procedures of Appointment of Official Veterinarian at the United States-eligible establishment and related on the job training under a senior veterinarian, and
- Training record of participants in a training on *Listeria* management organized by Ministry of Health, Italy the summer of 2014 held in Parma Italy.

Any new FSIS information received at the Department of Prevention is first analyzed and then sent through supervisory chain of command to the inspectors via e-mails, which is followed by hard copies. The FSIS auditor verified the CCA has mechanism to disseminate any new information to inspection officials and the establishment in timely manner.

Without prejudice to the EU legislation, San Marino applies special conditions to meet FSIS import requirements. San Marino has issued Decree n. 32 of 09/03/2005, amended and supplemented by Decree n. 70 of 29/06/2012, to enforce the FSIS' requirements for HACCP and Sanitation SOP. The CCA, under a separate letter to the establishment eligible to export to the United States, directed that latter needs to refer to FSIS Compliance Guideline, "Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products," and develop procedures to meet the requirements of 9 CFR Part 430. Through document review at the CCA headquarters, local inspection office, and the at the United States-eligible establishment, in conjunction with the interviews conducted at these audit sectors, the auditor verified that San Marino requires the establishment to develop and implement, Sanitation SOP, HACCP and procedures to comply with the requirements consistent with 9 CFR Parts 416, 417, and 430, respectively.

In order to verify the CCA's ability to provide adequate administrative and technical support to operate the inspection system, the auditor evaluated the documentation submitted by the CCA with its SRT, as well as his own on-site record reviews, interviews, and observations at government offices, at the laboratory conducting microbiological testing, and in the audited establishment. As stated earlier in the component, the Public Health Laboratory, the U.O.S.-Laboratorio Di Sanita Pubblica, is one of the four functional components of Department of Preventions. The CCA requires that the laboratory maintain

operating standards and requirements in accordance with ISO 9001 specification. Det Norske Veritas (DNV), an internationally known accrediting body, conducts the annual audit of the laboratory. The DNV audits verify that the laboratory maintains an adequate internal quality control program, including analyst qualification and training. The CCA routinely reviews the annual ISO 9001 certification report and ensures that findings of annual audits of the laboratory have been corrected in timely manner.

The CCA has adopted FSIS' Microbiological Laboratory Guideline (MLG) 8.09 method to analyze RTE product for the presence of Lm. The MLG methods are also employed to test samples drawn from food contact surface, nonfood contact surface, and the processing environment for the presence of *Listeria spp.* The CCA requires of the laboratory that all product samples be tested for presence or absence of *Salmonella spp.* using FSIS MLG 4.08 (revised) analytical method.

Based on the on-site audit observations, document reviews, and interviews conducted at all audit sectors, in conjunction with the review of the SRT and associated supporting documents, FSIS concludes that the CCA continues to maintain equivalence and is operating at an average level of performance.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS's requirements, including but not limited to, HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to the establishments certified eligible to export to the United States. There are no regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

The evaluation of this component included an analysis of information provided by the CCA, in the SRT, as well as interviews and observations during the on-site portion of the audit. The FSIS auditor verified that official inspection and verification activities were conducted in accordance with the responses in the SRT and supporting documentation.

The national law of 29 October 1992, n. 85, titled "rules of hygiene in production, storage, transport, sale, and supply of food and drinks," delegates the legal authority in the inspection system to enforce food hygiene laws and regulations. The principle and requirements of food law and procedures pertaining to food safety are contained in Delegated Decrees 29 June 2012 n 68 and n 72, which authorize the inspection system to transpose the EU Regulation 854/2004 in regard with specific rules for the organization of official controls on products of animal origin intended for animal consumption. The food hygiene decree of June 29, 2012 n 70 allows the government to adopt Regulation 852/2004 Annex II into the national food hygiene law and as a result requires the establishment to develop procedures in accordance with the previously mentioned EU regulation. In addition, San Marino has issued Decree n. 32 of 09/03/2005, amended and supplemented by Decree n. 70 of 29/06/2012, to enforce the United States' requirements for HACCP and Sanitation SOP. Under the provision of the aforementioned decree, San Marino requires that the United States-eligible establishment develop and implement procedures for SPS and Sanitation SOP consistent with the requirements in 9 CFR Part 416.

During the headquarters' audit, the FSIS auditor verified that Law of 29 October 1992, n. 85 and all the decrees issued in connection with the law empower the CCA to enforce rules of hygiene in production of food, storage, transport, and sale for the public. The CCA has issued the following delegated decrees to transpose the specific EU legislations into its inspection system:

- The decree 72 of June 29, 2012 to transpose specific rules of Regulation 854/2004 for the organization of official controls on products of animal origin intended for animal consumption legislation,
- The decree 70 of June 29, 2012 "Food hygiene" is on the transposition of EU Reg. 852/2004 Annex II, and
- The decree 71 of 29 June 2012 "Rules on specific hygiene rules for food of animal origin" is authority to transpose the requirement contained in Reg. 853/2004 Annex III.

Without prejudice to the EU legislation, San Marino applies special conditions to meet FSIS import requirements. San Marino has issued Decree n. 32 of 09/03/2005, amended and supplemented by Decree n. 70 of 29/06/2012, to enforce the United States requirements for HACCP and SSOP. Requirements for *Listeria* control in RTE products exposed to processing environment for additional processing steps after receiving lethality treatment are contained in the CCA's communication "Prot. n. 3226/DSP-V2/2014. This communication specifically requires the RTE-establishment to implement procedures that conform to the requirements of alternative 3<sup>1</sup> as specified in 9 CFR Part 430.

Through record review of establishment's internal control documents and the verification of inspection records, the FSIS auditor verified the official controls exercised over condemned material at the establishment eligible to export to the United States. San Marino has implemented the specific provisions of Regulations (EC) 1774/2004, 852/2004 and 853/2004 on requirements concerning the official control on condemned material. The auditor verified that for the establishment eligible to export to the United States, the CCA has adopted FSIS regulatory requirements within the meaning of 9 CFR 327.2. These requirements are enforced at the United States certified establishment through official communication to the establishment.

Some core criteria of the Statutory Authority and Food Safety Regulations component that an exporting country needs to meet pertaining to humane handling and slaughter of livestock, ante-mortem inspection, postmortem of carcasses, and parts do not apply to San Marino's inspection system. Animal Plant Health Inspection Service (APHIS) recognizes San Marino as undetermined risk for Classical Swine Fever (Hog Cholera), affected with Swine Vesicular Disease, and free from African Swine Fever, and Foot & Mouth Disease (but with special restrictions). Currently San Marino resources its raw meat supply from the United States-eligible establishments in Italy.

At the CCA headquarters, the FSIS auditor verified that the CCA exercise its regulatory authority, as outlined in national legislation and regulations, to enforce the EC Regulations or third country import requirements including those of the United States. While verifying the core criteria regarding controls over establishment construction, facilities, and equipment, the auditor reviewed specific sections of national laws relevant to meat inspection authority. The auditor confirmed that the CCA draws its authority from Decree n. 32 of 09/03/2005 (amended and supplemented by Decree n. 70 of 29/06/2012), to enforce the United States' requirements for HACCP and Sanitation. In order to enforce the

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<sup>1</sup> Alternative 3 is one of the three alternatives to control *Listeria monocytogenes* in post-lethality exposed ready-to-eat product. This alternative relies on controlling Lm sanitation measures.

requirements for Sanitation in the United States-eligible establishment, the CCA required that the establishment to develop and implement procedures in compliance with 9 CFR Part 416. Under the authority of the previously mentioned decree, the CCA issued the sanitation requirements to the establishments certified as eligible to export the United States through an official communication. Any violation of the official communication may result in enforcement actions ranging from retaining product, rejecting equipment to suspension of eligibility to export.

The departmental personnel conduct periodic supervisory reviews every month. These supervisory reviews are conducted using a standard format called the "Periodical Supervisor Schedule." This form provides the supervisor a checklist to be followed when conducting reviews of establishment's food safety programs and verification of the OV inspection activities. The supervisory reviews focus on SOP/SPS, SSOP, HACCP, and microbiological sampling and testing. Each area of focus in the form has its own separate section with its own checklist. The form also has a feature that allows the supervisor to include a detailed description of the finding when an activity is checked to indicate a concern. The last section in the review is reserved for the evaluation of the OV's performance during the reviewing period. This section is excluded from the copy of the report that is received by the establishment management. The OV is responsible for verifying and documenting the results of corrective actions effected because of a previous supervisory review. The supervisor also follows up on the implementation of corrective action during the subsequent supervisory visit at the United States-certified establishment. The results are documented in the subsequent review. The FSIS auditor reviewed the recent last three supervisory reports and concludes that reviews are conducted in accordance with standards established by the CCA.

Concerning the daily inspection at the United States-eligible establishment, the FSIS auditor observed the OV performing daily inspection verification activities at a time when the establishment was producing product for export to the United States. These daily verification activities include direct observation and review of establishment records of HACCP and SSOP and of other food safety records maintained by the establishment. The OV also verifies establishment's sample collection and submission of samples to the laboratory, and the OV reviews sample results for *Listeria monocytogenes* and *Salmonella*.

The outcomes of the inspection verification activity are documented on a weekly inspection record, "Schedule of Control." Any concern identified in the SOP/SPS, SSOP, HACCP, or microbiological sampling is expanded upon with much more detail about the nature and extent of the findings in the remarks sections. In the event a noncompliance is detected that is likely to pose public health concern, the OV takes enforcement action and issues a noncompliance record and follows up until the noncompliance is satisfactorily addressed. The FSIS auditor reviewed daily inspection record for most recent 90 days, compared with it with the establishment's food safety record for the same period, and concluded that the inspection system meets the criteria for daily official supervision of processing activities at the United States-eligible establishment.

San Marino's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those of the FSIS system of meat inspection in the United States. The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an average level of performance.

## VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the on-site portion of the audit, the auditor reviewed and analyzed information pertaining to the Sanitation component in the SRT. Once on-site, the auditor gathered additional information at the CCA headquarters office and one United States-eligible establishment.

The FSIS auditor reviewed establishment's programs and records related to the design and implementation of sanitation. The establishment has adopted alternative 3, as means to control pathogens known to contaminate RTE product exposed to the post-lethality processing environment. The establishment has developed and implemented procedures to maintain sanitation consistent with requirements specified in 9 CFR Part 430 to address *Listeria monocytogenes* and *Salmonella* hazards in fully cooked ham product, which is packaged after receiving lethality.

The FSIS auditor verified the actual pre-operational inspection by observing the OV conducting pre-operational sanitation verification of the establishment. The OV's hands-on verification procedures begin after the establishment personnel conducted pre-operational sanitation and determined that the facility is ready for the OV pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the CCA's established procedures.

The FSIS auditor observed the OV conducting verification of operational sanitation procedures at the audited establishment. These verification activities include direct observation of operations and review of the establishment's associated records. The audited establishment maintained sanitation records sufficient to document the implementation and monitoring of the Sanitation SOP and any corrective actions taken. Based on the observations made by the auditor noted below, during the on-site visit to the establishment, he concluded that the establishment's sanitation monitoring and corresponding verification records for the period had discrepancies in the description of conditions of the audited establishment. The auditor noted that:

- In the receiving room, a clogged drain line had a potential for water to stagnate and cross-contaminate RTE product.
- Beaded condensation was around refrigeration pipes in the ingredient and spices room and other production areas.
- There was rust, peeling paint, and loose caulking in chillers and other establishment production areas, indicating neglect or poor implementation of the maintenance program.

The OV documented the deficiencies identified above and issued the audited establishment noncompliance record requiring immediate corrective actions to each of the findings.

FSIS determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOP. Based on the observations made on-site in conjunction with the analysis of objective evidence gathered during the audit, however, the FSIS auditor concludes that the CCA needs to correct deficiencies noted

in the findings. FSIS expects that the CCA appropriately address these audit findings within 60 days of issuance of the draft final audit report.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventive control plan to maintain equivalence.

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The document review and interviews conducted at the CCA's headquarters confirmed that the establishment eligible to export pork product to the United States required under the decree n. 32 of 09/03/2005 (amended) in conjunction with Decree n. 70 of 29/06/2012 to develop and implement HACCP system consistent with the regulations specified in 9 CFR Part 417. While onsite, the FSIS auditor reviewed the design and execution of HACCP plan of the audited establishment and confirmed that the establishment had taken all hazards associated with its post-lethality exposed RTE product operations into consideration.

The FSIS auditor further verified through record review and observation that the OV assigned to the only United States-certified establishment conducts daily verification of HACCP related procedures. HACCP verification activities by the OV include the evaluation of written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification of Critical Control Points (CCP) verification. These verification activities are conducted by the OV once a week during the days no production for the United States is occurring and on the daily basis when production for the United States export is planned. As a part of audit activity, the FSIS auditor verified that the audit findings identified on the last FSIS audit pertaining to HACCP component had been implemented. The following HACCP related findings were identified during the last FSIS audit of San Marino conducted in 2008:

- In the audited establishment, the critical limit for a critical control point was not being monitored and documented.
- In the establishment audited, corrective actions pertaining to instrument calibration were not being documented.

The FSIS auditor verified that the certified establishment had developed, implemented, and maintained an equivalent HACCP system in accordance with the aforementioned laws, regulations, and procedures. There were no HACCP deviations identified during the audit. The CCA enforces the implementation of the HACCP regulatory requirements in the audited establishment. The analysis and on-site audit verification indicate that the CCA's meat inspection system continues to maintain equivalence and is operating at an average level.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAM**

The FSIS criteria for this component include the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. To be equivalent, the program needs to include random sampling of internal organs, muscle

meat, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the process used to design the plan; a description of the actions taken to address unsafe residue as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

In order to meet the requirements of chemical residues control program San Marino relies on Italy's National Residue Monitoring Program (NRMP) as the country receives its raw pork product from the United States-certified slaughter/processing establishments in Italy. The CCA routinely reviews Italy's NRMP and pays special attention on performance of the United States-eligible Italian slaughter establishments supplying raw meat to San Marino. The establishment under purchase agreement also reviews the results of chemical residue testing of its supplier of raw pork meat products. The auditor verified during the on-site visit to the establishment that the establishment's HACCP program addresses hazards associated with chemical and environmental residues in accordance with the control measures identified in purchase requisitions. The terms of the requisition require the supplier to address chemical and environmental residues in the raw product in accordance with the San Marino's national residue program and in accordance with EU regulations, EC Directives 96/22 and 96/23.

The analysis and on-site audit verification indicate that the CCA's meat inspection system continues to maintain equivalence and is operating at an average level of performance.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The FSIS auditor confirmed that the San Marino's establishment adequately addressed all microbiological, chemical, and physical hazards associated with raw meat product in its HACCP plan. San Marino sources its raw pork product from Italy. The United States-eligible establishment, under a purchase requisition, obtains fresh raw pork meat product from United States-certified slaughter establishments. The purchase requisition guarantees that the product has been produced under a validated HACCP plan and that all physical, chemical and biological hazards associated with the slaughtering /processing have been addressed.

During the audit of the headquarters, among the documents evaluated, the auditor reviewed a letter titled "RSM, 06/05/2014/1713 d.f.R Prot. N. 3226 / DSP-V2 / 2014" issued to the exporting establishment. The letter is an official instrument to enforce HACCP and Sanitation SOP procedures in order to meet the requirements consistent with 9 CFR Parts 417 and 416. The document further states that the establishment needs to refer to FSIS compliance guidelines for controlling *Listeria monocytogenes* in post lethality exposed RTE meat product on how to implement the requirements as specified in 9 CFR Parts 416, 417, and 430.

The FSIS auditor reviewed the microbiological verification testing program employed by San Marino on its RTE product destined for the United States. As an audit verification activity, the FSIS auditor evaluated documents at the CCA's headquarters, government laboratory, and the local inspection office. The design of the testing program includes testing of the RTE product, food contact surface, non-food contact surface, and testing of processing environment for *Listeria monocytogenes* or *Listeria spp.* as applicable. Pertaining to the frequencies with which this testing is conducted, the CCA has made recent changes. In addition to one product test per month, during a year, the establishment will be subjected to three annual tests conducted randomly. The design of the testing also includes sampling and testing of food contact surfaces (FCS), indirect food contact surfaces (IFCS) such as aprons or equipment, and non-food contact surface (NFCS) or environmental. The annual plan for the above cited testing follows as under:

- FCS-9 analytical tests,
- IFCS-3 analytical tests, and
- NFCS-3 one sample represents pre-operating conditions and the other two represents the operating conditions.

The review of establishment's own microbiological verification testing program of its post-lethality exposed RTE product revealed that the establishment employs alternative 3 to control *Listeria* hazard through sanitation. The monthly testing regimen includes testing of product, FCS, IFCS, and NFCS. Ten samples are collected from pre-identified FCS units, seven of which are collected during operation and three prior to operation to assess the efficacy of sanitation controls. In addition to FCS, each month two samples are collected from various units of the processing environment and three samples from non-food contact surfaces. All product samples are tested for presence or absence of *Salmonella spp.* and *Listeria monocytogenes* using ISO 18593:2004 and FSIS-Microbiological Laboratory Guide (MLG) 8.09, respectively. The latter method is also used to detect *Listeria spp.* on swabs collected on FCS, IFCS, and NFCS samples. The FSIS auditor examined samples of test results, sanitation, and corrective action in relation to the RTE program for the last three months. For the same period, the auditor chose to review verification record and other inspection activity conducted by the official inspector. The FSIS auditor did not identify any concerns with the establishment microbiological testing program.

Based on the evaluation of the testing program the FSIS auditor concluded that San Marino had sampling and testing program to ensure the product for the United States export is free of *Salmonella* and *Listeria monocytogenes* in RTE products.

The evaluation of this component also included an on-site audit of the official microbiological testing laboratory "The Unita Organizzativa Semplice (U.O.S.)-Laboratorio Di Sanita Pubblica." This laboratory conducts testing on product destined for the United States to detect *Salmonella spp.* in RTE product using FSIS' method MLG 4.08 (Revised) and employ FSIS' method MLG 8.09 2013 to detect for *Listeria monocytogenes*. For the detection of *Listeria spp.* on FCS, IFCS and NFCS the laboratory use FSIS' method MLG 8.09 2013. The audit of the laboratory examined the analyst qualifications, sample receipt, timely analysis, analytical methods, analytical controls, recording and reporting of results, calibration of equipment; internal audits; traceability of samples and sample analysis; test kits; and intra and inter-laboratory testing. This laboratory participates with Istituto Zooprofilattico dell' Abruzzo e del Molise "G. Caporale" Teramo on inter-laboratory testing. The two laboratories also collaborate on confirmation process any time San Marino identifies a presumptive positives for *Listeria*

*monocytogenes*. The Teramo laboratory conducts Pulse-field gel electrophoresis (PFGE) confirmatory tests for San Marino and catalogues the isolates for them.

The laboratory personnel are responsible to collect the samples under supervision of San Marino's law enforcement authority to ensure sample tempering or security breach does not occur during sample collection and transportation. The auditor observed the laboratory technician taking a RTE sample at the establishment using aseptic technique outlined in sample collection procedures.

Currently the laboratory receives annual audits as part of inspection system's ISO 9001 certification by Det Norske Veritas (DNV), an internationally known accrediting body. The DNV auditors conduct audit of the entire inspection system including the microbiological laboratory the U.O.S.-Laboratorio Di Sanita Pubblica to determine whether the inspection system maintains the requirement of the certification. Some of the salient features of the ISO 9001:2008 based quality management include: leadership, process approach, system approach continual improvement, and fact-based decision-making. The laboratory portion of DNV report generated in 2013 was reviewed and found to comply with the standards.

The interviews with the management of the government-owned laboratory and the CCA of San Marino revealed that the laboratory is scheduled for ISO 17025 accreditation audit in November by "ACCREDIA," the Italian National Accreditation Body appointed by the State to perform accreditation activity. On April 22, 2015, San Marino notified FSIS, that the ACCREDIA granted its microbiological laboratory accreditation on February 7, 2015, after the laboratory met the requirements for the certification for "EN ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories Standards."

The FSIS auditor reviewed training materials and records and the results of proficiency testing. No concerns were noted for the Microbiological Testing Programs Component. Therefore, the CCA continues to maintain equivalence and is operating at an average level of performance.

## **X. CONCLUSIONS AND NEXT STEPS**

The 2014 audit results indicate that the CCA's food safety inspection system is performing at an overall average level meeting the core criteria for all six equivalence components. The FSIS auditor did not identify any concerns in five equivalence components. However, FSIS identified operational (or procedural) weaknesses related to Sanitation that need to be addressed by San Marino's inspection system.

During the exit meeting on July 25, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term prevention of recurrence of on-site audit findings. FSIS will evaluate any information provided by the CCA including the submittal of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions.

# **APPENDICES**

**APPENDIX A: Individual Foreign Establishment Audit Checklist**

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION San Marino Salumi Str. Del Lavoro 45 Gualdicciol San Marino	2. AUDIT DATE 07/22/2014	3. ESTABLISHMENT NO. RSM2L	4. NAME OF COUNTRY San Marino
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 07/22/2014 Est # RSM 2L a processing establishment

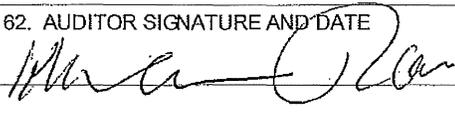
- 39/51 a) Beaded condensation was around refrigeration pipes in the ingredient and spices room and other production areas.
- b) Rust, peeling paint, and loose caulking were observed in chillers and some production areas in the establishment indicating neglect or poor implementation of maintenance program.
- 42/51 In the receiving room, a clogged drain line had a potential for water to stagnate and cross-contaminate RTE product.

Commitments for corrective actions were provided by the supervisor who led the audit of the establishments.

61. NAME OF AUDITOR

AlamKhan, DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan DVM 07/22/2014

**APPENDIX B: San Marino's Response to Draft Final Audit Report**



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



San Marino, 02/07/2015 /1714 d.F.R  
Prot. n. 4844/DSP/V-2/2015

U.O.S. Sanità veterinaria e Igiene alimentare

Dr. Shaukat H. Syed  
Director International Audit Staff  
Office of Investigation, Enforcement and  
Audit  
Food Safety and Inspection Service  
1400 Independence Avenue, SW.  
Washington, D.C.  
20250 USA

**Oggetto: Comments regarding 2014 FSIS Audit Report**

Dear Dr. Shaukat H. Syed,

answering to your electronic mail of May 12 2015, we inform you that Establishment San Marino Salumi SM 2L CE Alternative 3 absolved largely all the improvements we asked after FSIS 2014 Exit Audit about:

**POINT VI. COMPONENT THREE: SANITATION**

In this case we communicate that:

- the clogged drain line of the receiving room have been reactivated and painted;
- In the Ingredient room all refrigeration pipes have been repaired;
- specific maintenance works of all refrigeration pipes have been made in almost all production areas while other general maintenance works continue according to an approved program.

The Direction of the establishment is going to improve maintenance everywhere as to eliminate rust, condensation, peeling paint, loose caulking and for this reason it has established a new maintenance program. See the attached file

**Regarding to POINT IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

we inform that the testing program on RTE products destined to USA employed by Official Vet of San Marino Republic, is now conformed to the Official Italian Government Program for Lysteria and Salmonella. This Official Program includes yearly samples as follows :

- RTE PROD RISK : 1 COOKED HAM SAMPLE EACH MONTH
- RTE PROD RAND : 3 RTE EXTRA RANDOM PRODUCT TEST
- RLM : 1 YEARLY SINGLE environmental and product SAMPLE composed by: 10 FCS + 3 INFCS + 2NFCS + 5 COOKED HAMS made on the sampled surfaces.

Best regards

Il responsabile U.O.S Sanità Veterinaria e Igiene Alimentare

Dr. Antonio Putti

**REPUBBLICA DI SAN MARINO**

Sede legale del Dipartimento Prevenzione

Via Scialoja 20  
47893 Borgo Maggiore  
Repubblica di San Marino

Sede tecnica del Dipartimento Prevenzione

Via La Toscana 3  
47893 Borgo Maggiore  
Repubblica di San Marino  
T. +378(0549)994505- F +378 (0549) 994355  
e-mail info.dp@iss.sm  
www.salute.sm

Sede distaccata UOS Sanità Veterinaria  
e Igiene Alimentare

Strada del Lavoro 29  
47892 Guadicciole  
Repubblica di San Marino  
T. +378 (0549) 904614- F + 378 (0549) 953966

