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United States Department of Agriculture

Food Safety and
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Dear Dr. Berardi,

The Food Safety and Inspection Service (FSIS) onsite audit conducted from March 6 through March 10, 2017, supports that San Marino's processed pork inspection system continues to remain equivalent to that of the United States. 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.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

SAN MARINO

MARCH 6 - 10, 2017

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

August 9, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 6 - 10, 2017. The purpose of the audit was to determine whether San Marino's food safety system governing processed meat (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 currently exports fully cooked—not shelf stable pork products (e.g., hams, loins, and bacon) to the United States.

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

The FSIS auditor identified systemic weaknesses with the Central Competent Authority's (CCA) *Department of Prevention* in its conducting of government HACCP verification procedures. The following noncompliances were not identified earlier by the CCA at the audited pork processing facility:

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) §417.3(a). However, the specific actions set forth did not include all four parts of the required corrective actions stated in the regulation.

These noncompliances did not result in any immediate concerns regarding the safety of product currently in the facility or previously exported to the United States. During the exit meeting, the *Department of Prevention* presented evidence that it had taken immediate measures to resolve the identified noncompliances, including issuance of noncompliance reports and verification that the food business operator had modified its HACCP program accordingly.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY 1

III. BACKGROUND 3

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION) 3

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) 6

VI. COMPONENT THREE: GOVERNMENT SANITATION 7

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM 8

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS 10

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS 10

X. CONCLUSIONS AND NEXT STEPS 12

APPENDICES 14

Appendix A: Individual Foreign Establishment Audit Checklist

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

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of San Marino's food safety system from March 6 - 10, 2017. The audit began on March 6, 2017, with an entrance meeting held in San Marino, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the *Department of Prevention.*

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing processed meat (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.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes San Marino as affected with classical swine fever (hog cholera) and swine vesicular disease, and free from African swine fever and foot & mouth disease (with special restrictions). San Marino is eligible to export processed pork to the United States. Currently, San Marino sources its raw meat supply from the United States-eligible establishments in Italy and Denmark.

The 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) 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 a self-reporting process.

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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions 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 one establishment in San Marino that is eligible to export to the United States was audited. During the establishment visit, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory

reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat.

Additionally, the FSIS auditor examined a government microbiology laboratory to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• San Marino
Laboratory		1	• Government microbiology laboratory, San Marino
Pork processing establishment (local inspection office)		1	• San Marino Salumi S.r.I.; Est # SM CE 2L, San Marino

The audit was undertaken 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.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of San Marino's inspection system for processed 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 Sanitary/Phytosanitary Agreement.

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

- 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.

III. BACKGROUND

San Marino currently exports fully cooked—not shelf stable pork products (e.g., hams, loins, and bacon) to the United States. From October 2013 to September 2016, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 66,871 pounds of processed pork exported by San Marino to the United States. FSIS also performed reinspection on 26,304 pounds at POE for additional types of inspection (TOI), of which no product was rejected.

The previous FSIS audit (2014) identified several findings related to *Component 3: Government Sanitation* at the one pork establishment that is certified to export to the United States. As the current audit included a return visit to the same facility, the FSIS auditor was able to verify that all previous findings had been adequately resolved.

The FSIS final audit reports for San Marino's food safety system are available on the FSIS Web site 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 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[1] where products are prepared for export to the United States.

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT), interviews, and observations during the onsite audit.

San Marino is an independent republic situated on the Italian peninsula on the northeastern side of the Apennine Mountains. San Marino applies the standards found in EC regulations pertaining to food of animal origin, including *EC Regulation 178*, *EC Regulation 854*, *EC Regulation 882*, and other EC regulations relevant to product of animal origin. Additional requirements related to United States export not covered in the EC regulations are implemented through specific governmental issuances without prejudice to EC regulations.

[1] Although there is currently only one establishment in San Marino which is certified for export to the United States, the term “establishments” will be used throughout this document to reflect the fact that the CCA may, at its discretion, certify additional establishments at any given time. Moreover, all related procedures, policies, and regulatory requirements set forth by either FSIS or the CCA would consequently apply to the totality of certified establishments on a system-wide basis.

The meat inspection system in San Marino is grounded in a broad, complex organization known as the *Institute for Social Security* [*Istituto per la Sicurezza Sociale* (ISS)]. The *Secretary of State for Public Health*, who is supported by the *General Manager* and an *Executive Committee*, heads the Institute. Within the ISS, the *Department of Prevention* [*Dipartimento Prevenzione*] serves as the CCA's department in charge of managing the overall regulatory oversight of food processing of animal origin.

The *Department of Prevention* is further divided into the following organizational units:

- Labor Medicine and Hygiene;
- Environmental Protection;
- Workplace Safety;
- Public Health Laboratory; and
- Veterinary Health and Food Hygiene (VHFH).

From an operational perspective, the unit that has the most bearing on the export of meat products is the VHFH. This unit includes the Official Veterinarians (OVs) assigned to the United States-eligible establishment as well as the supervisory staff. These individuals are employed directly by the government on a permanent basis. While onsite, this was verifiable through the review of readily available payment records, which clearly indicated a direct line of compensation between the ISS and VHFH inspection officials. There have been no significant organizational changes within the *Department of Prevention* since the last FSIS audit.

The FSIS auditor verified the CCA's adherence to *Law n.107 (2009)*, which provides regulations governing the recruitment standards in civil service employment in San Marino. This 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. *Title III* of this law establishes procedures on filling a career position with a potential for promotion within an agency. To be assigned as an OV in a processing establishment, the CCA ensures that the assigned veterinarian meets EU criteria established for the recruitment of veterinarians. These criteria on professional qualifications for veterinarians to work in meat inspection are outlined in *Chapter IV* (*points 1-7*). The FSIS auditor reviewed the procedures of appointment of the OVs assigned to the United States-eligible establishment and determined that the CCA followed the applicable national and EU regulations in the recruitment procedure.

The FSIS auditor noted that the CCA provides continuous training opportunities to its inspection force. Training attendance is documented on individual employee profiles [*Scheda Personale – Aggiornamento Professionale*]. A review of the profiles for the OVs assigned to the United States-eligible establishment indicated that they had participated in the following courses since the last FSIS audit:

- New Requirements for Food Processors and Restaurant Owners: September 2014;
- Export of pork products to the United States: September 2014;
- Product Labeling Seminar: October 2015;
- Official Verification Procedures: May 2016;
- Microbiological Safety of Products Exported to the United States: September 2016; and
- Exporting Products of Animal Origin (Refresher Course): October, 2016.

In addition, any new information received at the *Department of Prevention* from FSIS is first analyzed and then sent via e-mail through the supervisory chain of command and to the inspectors. The e-mail is followed by hard copies. The FSIS auditor verified that the CCA maintains mechanisms (e.g., e-mail) to disseminate any new information to inspection officials and the establishment in a timely manner.

The FSIS auditor's review of the CCA's *Protocol 0310UOS (2014)* and *Protocol 0512UOS (2016)* indicated that it provides a comprehensive outline of recall procedures to be followed by both industry and inspection personnel in the face of adulterated products destined for export to the United States. 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 as well as FSIS management of any affected product that is en route to the United States. No such recalls have occurred in recent history regarding product from San Marino.

Technical laboratory support for microbiological testing within San Marino's meat inspection system is provided through the government's *Public Health Laboratory*. In November 2014, this laboratory obtained *International Organization for Standardization (ISO) 17025: General Requirements for the Competence of Testing and Calibration Laboratories* accreditation through *ACCREDIA*, an Italian organization appointed by the CCA to perform accreditation activity. However, due to a series of staffing shortages that began in the latter part of 2015 and included the loss of two chemists, two microbiologists, and a member of the administrative staff, the laboratory was unable to maintain *ISO 17025* accreditation, which expired in February 2017.

FSIS expects laboratories to ensure accurate testing and maintain sufficient personnel so as to provide for an uninterrupted implementation of its testing programs. The FSIS auditor noted the following elements demonstrating ongoing oversight of the laboratory system, for which ultimately no concerns were identified:

- The government laboratory continues to operate under its quality manual and procedures developed in association with the initial *ISO 17025* accreditation process.
- The CCA has developed specific protocols in its *PGL 03 Rev.2, Sampling Cooked Hams Destined for United States Export (2017)*. This document provides detailed instructions for sample selection, transport, receipt, analysis via current FSIS Microbiology Laboratory Guidebook (MLG) methods, reporting of results, and follow-up testing.
- Review of the laboratory record *Mod569rev2L* indicated that all government samples collected in accordance with the national sampling plan had been tested as planned, with reasonable turnaround (reporting of results) times.
- Two new microbiologists were hired in January 2017. The FSIS auditor's review of the documentation associated with the hiring process indicated that they had met the necessary educational and training requirements, in accordance with the laboratory's *ISO 17025* quality manual.
- The CCA presented documentary evidence demonstrating an intent to reestablish *ISO 17025* accreditation through *ACCREDIA* in November 2017.

Additional information regarding FSIS' assessment of the *Public Health Laboratory* is provided under *Component 6: Government Microbiological Testing Programs.* The FSIS auditor concluded that the CCA continues to organize and administer its meat inspection system in a manner that meets the core 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; daily inspection; and periodic supervisory visits to official establishments. There are no regulatory changes associated with the export of processed pork products since the last FSIS audit that would have required changes by the CCA.

The national law, *Rules of Hygiene in Production, Storage, Transport, Sale, and Supply of Food and Drinks (October 1992, n. 85),* delegates the legal authority in the inspection system to enforce food hygiene laws and regulations. The principal requirements of food law and procedures pertaining to food safety are contained in *Delegated Decrees n. 68* and *n. 72 (June 2012),* which adopt *EC Regulation 854/2004* for the organization of official controls on products of animal origin intended for human consumption. In addition, *Food Hygiene Decree n. 70 (June 2012)* adopted *EC Regulation 852/2004, Annex II* into the national food hygiene law.

The FSIS auditor noted that the OV verifies that each shipment of source meat used for the production of cooked hams originates only from establishments certified for export to the United States, which currently includes establishments in Italy and Denmark. 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. In addition, product destined for export to the United States is clearly identified and segregated through all stages of production, storage, and shipment within the establishment's recordkeeping system. Lastly, the CCA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS Web site in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. This chart can be found at: https://www.fsis.usda.gov/wps/wcm/connect/4872809d-90c6-4fa6-a2a8-baa77f48e9af/Countries_Products_Eligible_for_Export.pdf?MOD=AJPERES.

The FSIS auditor reviewed the outcomes of daily inspection verification activities documented on San Marino's "*Schedule of Control*." By cross-referencing these documents with establishment production records, FSIS was able to ascertain that daily inspection was provided whenever production for the United States was occurring. Furthermore, in cases where noncompliances were identified, the FSIS auditor noted that the OV took appropriate enforcement action by issuing noncompliance records and conducting the necessary follow-up to ensure that the noncompliances were satisfactorily addressed.

The control of condemned materials is accomplished through application of *EC Regulations 1069/2009* and *142/2011*. During the audit, FSIS verified that the relevant portions of this regulation were applied, including: a) appropriate identification in accordance with the categories described therein; b) segregation in specially-marked or otherwise secure containers; and c) final documented disposal of these materials at nearby rendering facilities.

In accordance with *Protocol n. 3169/DSP-V2 (2017)*, departmental personnel conduct periodic supervisory reviews at a minimum frequency of at least four times per year. Prior to issuing this procedure in the early part of 2017, supervisory reviews were conducted on a monthly basis. Apart from the modification in frequency, the revised procedure also introduced changes in the methodology by which these supervisory reviews are conducted. This methodology is based on the procedure outlined in Italian Ministry of Health's *Appendix A: Manual of Official Controls in Establishments Certified for Export to the United States*. FSIS considers these modifications to the supervisory review program timely in that many of the basic noncompliances outlined under *Component 4: Government HACCP Systems* should have been identified during prior supervisory reviews. *Section 5.3 HACCP* of the aforementioned procedure provides detailed verification activities related to those elements of basic HACCP compliance where problems were identified by FSIS during the current audit (e.g., contents of the HACCP plan, including description on ongoing verification activities and their intended frequencies). The CCA implementation of these new procedures should facilitate their ability to systematically identify and resolve similar noncompliances in the future.

San Marino's meat inspection system continues to maintain the legal authority and a regulatory framework, which as described, is consistent with criteria established for this component.

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 standard operating procedures to prevent direct product contamination or insanitary conditions.

The FSIS auditor verified that the CCA uses its legal authority to require that its certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Without prejudice to the EC legislation, the CCA has issued *Decree n. 70 (2012)*, which applies special conditions at facilities that are certified to export to the United States. This document instructs establishments to comply with the requirements outlined in 9 CFR Parts 416 and 430 (i.e., the principal regulations for sanitation and the control of *Listeria monocytogenes* (*Lm*) in FSIS-regulated facilities in the United States).

In addition to the basic requirements outlined above, the CCA has instituted specific requirements for sanitation in establishments producing post-lethality exposed RTE product in the circular *DGISAN 35655-P (9/16/2015).* This document has been adopted from the Italian Ministry of Health and was previously reviewed by FSIS in association with the 2016 audit of Italy. As per this document, establishments are required to verify sanitation by testing food contact surfaces (FCS) for *Lm* or indicator organisms, and also are to develop a surveillance

program for *Lm*, which must be included in the establishment's HACCP, sanitation standard operating procedures (SSOP), or other prerequisite program. If a product or FCS tests positive for *Listeria* spp., the product is considered adulterated and cannot be exported to the United States. Reconditioning of a product for United States export is prohibited. The document also contains specific requirements concerning the handling of products, appropriate use of paper towels in the post-lethality environment, and steps to be taken when product, FCS, or non-food contact surface (NFCS) samples test positive for *Lm* or an indicator organism. FSIS noted that the audited establishment adopted *alternative 3* (sanitation only) as the means to control post-lethality exposure to *Lm* in its fully-cooked pork products that are exported to the United States.

The FSIS auditor observed in-plant inspection verification of pre-operational and operational SSOP at the audited establishment. Audit evidence was gathered through direct observation of establishment operations and a review of the establishment's associated records. The FSIS auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The establishment maintained sanitation records sufficient to document daily implementation and monitoring of the SSOP and any corrective actions taken. No concerns arose as a result of these document reviews.

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

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan.

Without prejudice to the relevant EC regulations for HACCP, the CCA has issued *Decree n. 70 (2012)*, which applies special conditions at facilities that are certified for export to the United States. This document instructs establishments to comply with the requirements outlined in 9 CFR Parts 417 and 430 (i.e., the principal regulations outlining HACCP requirements and the control of *Lm* in FSIS-regulated facilities in the United States).

While onsite, the FSIS auditor reviewed the design and execution of the audited establishment's HACCP plan and confirmed that the establishment had considered all hazards associated with its post-lethality exposed RTE product (fully-cooked pork) operations. The establishment had adopted and was adhering to the lethality and stabilization performance standards outlined in *Appendices A and B* of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products*.

The FSIS auditor further verified through record review and observation that the OV conducted regular 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 confirmation of CCP verification. These verification activities are

conducted by the OV with a minimum weekly frequency and on a daily basis when production for the United States export is occurring.

However, FSIS noted the following basic HACCP noncompliances, which were not identified earlier by the CCA at the audited pork processing facility as part of the evaluation of written HACCP programs described above:

- The critical limit for 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 that was added to the brine mixture (this was the point that was actually being measured, rather than the concentration in the final product). A review of product formulation records indicated that acceptable values of nitrites were consistently used, for which the safety of product could be demonstrated. However, the failure of the establishment to accurately identify its CCP and related monitoring procedures does not meet the regulatory requirements of 9 CFR 417.2(c) (2).
- 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. While the establishment maintained records demonstrating that calibration was occurring within its various prerequisite programs, 9 CFR 417.2(c) (7) requires that ongoing verification procedures and the frequency at which they occur be outlined within the contents of the HACCP plan.
- 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 reference the *general* requirements outlined in 9 CFR 417.3(a). However, the specific actions set forth did not include all four parts of the required corrective actions stated in the regulation, as they did not provide mechanisms to ensure that a) the CCP is back under control after the corrective action is taken; and b) preventive measures are established. As there were no deviations from any of the establishment's CCPs in recent history, the safety of product produced by this facility was not called into question. Nevertheless, it is FSIS' expectation that establishments can readily demonstrate the ability to take appropriate corrective actions whenever deviations from the critical limit occur.

As indicated above, FSIS' analysis of these noncompliances did not result in any immediate concerns regarding the safety of product currently in the facility or of product previously exported to the United States. During the exit meeting, the *Department of Prevention* presented evidence that it had taken immediate measures to resolve the identified noncompliances, including issuance of noncompliance reports and verification that the food business operator had modified its HACCP program accordingly.

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 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 Italy's and Denmark's national residue monitoring programs, as the country receives its raw pork product from the United States-certified slaughter and processing establishments in these countries. The CCA routinely reviews the monitoring results of these countries as well as Europe's *Rapid Alert System for Food and Feed (RASFF)*, and maintains an open line of communication with the United States-eligible slaughter establishments in these countries.

The FSIS auditor verified during the onsite visit to the establishment that the establishment's HACCP program addressed hazards associated with chemical and environmental residues in accordance with the control measures identified in purchase requisitions. Additionally, the establishment reviewed the results of chemical residue testing of its suppliers of raw pork meat products. The terms of the requisition require the suppliers to address chemical and environmental residues in the raw product in accordance with *EC Directives 96/22* and *96/23*.

FSIS audits of the meat inspection systems for both Italy and Denmark were conducted in 2016, for which no significant finding related to the control of chemical residues was identified. Furthermore, there have not been any POE violations from San Marino, Denmark, or Italy related to this component since their last FSIS audits.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome. There have not been any POE violations related to this component since the last FSIS audit.

The CCA considers *Lm* to be a hazard of concern in the production of RTE products that are post-lethality exposed to the environment. Specific requirements related to *Lm* control are contained in *DGISAN 35655-P (9/16/2015)*, replicating the controls in 9 CFR 430.4 by providing the same three alternative controls to prevent post-lethality *Lm* adulteration in exposed RTE product. *Section A.4.1* of this document prohibits the export of any RTE product to the United States that is either contaminated with *Listeria* spp. or has come into direct contact with an FCS that is contaminated with *Listeria* spp. Furthermore, this document requires all United States-eligible establishments to operate under a single microbiological standard (zero-tolerance) for

Lm on product and product contact surfaces regardless of whether they are actively producing for the United States market at a given time.

Section C of *DGISAN 35655-P (9/16/2015)* outlines specific requirements for official verification of establishment RTE control programs. *Section C.1.b* addresses verification of the post-lethality treatments and processes used to eliminate or suppress the growth of *Lm* in RTE products in conjunction with specific risk alternatives chosen by the establishment. *Section C.1.c* outlines procedures for the verification of sanitation and HACCP requirements, with special emphasis on the control of *Lm* in RTE products and verification of establishment RTE sampling plans. *Section C.1.1.d* specifies enforcement actions to be undertaken in the face of positive results identified either through establishment or government verification testing.

The FSIS auditor verified that the CCA implemented the 2017 official surveillance plan for monitoring *Lm* and *Salmonella* in pork products to be exported to the United States as outlined in *Protocol N. 1882 DSP-V2/2017*. This plan includes the random and risk-based sampling of all RTE products for both *Lm* and *Salmonella*; as well as *Lm* monitoring of FCS, indirect food contact surfaces (IFCS) such as aprons or equipment, and NFCS in accordance with the following sampling plans:

- **RTE PROD RISK**: one cooked ham, monthly;
- **RTE PROD RAND**: one random product (cooked ham, loin, or bacon), yearly; and
- **RLm**: 10 FCS + 3 IFCS + 2 NFCS + 5 additional products, yearly.

Microbiologically independent lots of product destined for export to the United States are held during all phases of sampling (FCS, IFCS, NFCS, and product). All official analyses are conducted using current FSIS MLG methods. No concerns arose from the FSIS auditor's review of the government's testing program.

As indicated previously, San Marino's inspection system requires that establishments operate under a single microbiological standard (zero-tolerance) for *Lm* on product and product contact surfaces, regardless of whether they are actively producing for the United States market at a given time. While onsite, the FSIS auditor was able to verify that this was effectively being implemented through the review of records associated with production of cooked hams not intended for United States export, whereby an FCS (conveyor belt) tested positive for *Lm* during establishment testing. In this case, the FSIS auditor was provided with sufficient evidence to demonstrate the following:

- Segregation of product, with a focus on microbiological independence of the lots in question, and immediate suspension of export of any similar products to the United States. As per *Annex 3* of *DGISAN 35655-P (9/16/2015)*, the CCA defines the production lot as the quantity of product that has to be taken into consideration if a positive finding is obtained on a product or FCS. If a product or FCS is identified as positive for *Lm*, the production lot must be recalled if it has already been placed on sale.
- For this purpose, production lots are generally identified as the quantity of product processed between complete clean-up operations (clean-up to clean-up), unless the plant is able to manage smaller lots. A lot size may be reduced if the plant is able to implement a complete action of clean-up and sanitizing before its normal clean-up operation (based on its SSOP cleaning and sanitizing procedures).

- To determine a lot size, it is necessary to consider various factors including the origin of the materials used for RTE production, the frequency of cleaning and sanitizing, and the production stages. In any case, the processes must be recognized as suitable (validated) to restore generally sanitary hygienic conditions and, specifically, to guarantee the elimination of the environmental pathogens and guarantee the microbiological independence between two production lots.
- Disposal of the affected product.
- Documented activities conducted by industry to identify the source of the contamination.
- Intensified industry sampling, in accordance with *DGISAN 35655-P (9/16/2015), Section A.4.2.f.*
- Intensified government sampling in accordance with *DGISAN 35655-P (9/16/2015), Section A.4.2.f., Section C.2.b.*
- Performance of a documented supervisory review performed by an assigned task force of government officials.

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 of samples and sample analysis, and inter- and intra-laboratory testing. The FSIS auditor observed the laboratory technician taking an RTE sample using aseptic technique outlined in *PGL 03 Rev.2, Sampling Cooked Hams Destined for United States Export (2017).* This document also provides specific requirements regarding sample collection, integrity, and chain of custody, and testing methods to be used. The FSIS auditor noted that specific sections of these documents were being adhered to and that current FSIS MLG methods (i.e., MLG 4.09 and MLG 8.10) of analysis were being used on appropriate test portions. The results of inter-laboratory performance testing results for the last three years were available for review and indicated that the laboratory continued to maintain a high level (100%) of accuracy in its ability to identify both true negative and true positive results. No concerns were identified as a result of the visit to this facility.

San Marino's meat inspection system continues to maintain the regulatory framework for government microbiological testing, which as described, is consistent with criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 10, 2017, in San Marino with the *Department of Prevention*. At this meeting, the FSIS auditor presented the preliminary findings from the audit.

The FSIS auditor identified systemic weaknesses with the Central Competent Authority's (CCA) *Department of Prevention* in its conducting of government HACCP verification procedures. The following noncompliances were not identified earlier by the CCA at the audited pork processing facility:

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 reference the *general* requirements outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §417.3(a). However, the specific actions set forth did not include all four parts of the required corrective actions stated in the regulation.

These noncompliances did not result in any immediate concerns regarding the safety of product currently in the facility or previously exported to the United States. During the exit meeting, the *Department of Prevention* presented evidence that it had taken immediate measures to resolve the identified noncompliances, including issuance of noncompliance reports and verification that the food business operator had modified its HACCP program accordingly.

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.l. Strada del Lavoro – 45 47892 Gualdicciolo San Marino	03/07/2017	SM CE 2L	San Marino
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

15/51. 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 which was added to the brine mixture (this was the point that was actually being measured, rather than the concentration in final product). A review of production records indicated that acceptable values of nitrites were consistently applied, for which the safety of product currently in the facility and previously exported could be demonstrated. Furthermore, a review of analytical product testing results demonstrated that products typically contained less than 5 ppm for nitrites. However, the failure for the establishment to accurately identify its CCP and related monitoring procedures does not meet the regulatory requirements of 9 CFR 417.2(c)(2).

15/16/51. 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.

15/51. 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 reference the *general* requirements outlined in 9 CFR 417.3(a). However, the specific actions set forth did not include all four parts of corrective actions required by stated regulation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/07/2017

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

DIPARTIMENTO PREVENZIONE
Istituto per la Sicurezza Sociale

San Marino, 14/07/2017/1716 d.F.R
Prot. n. 8695 /DSP V2/2017

DIREZIONE

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Food Safety and Inspection Service
1400 Indipendence Avenue, SW.
20250 Washington, D.C.
U.S.A.

Oggetto : San Marino FSIS AUDIT 2017

Dear Jane H. Doherty,
We have the pleasure to inform you that the draft final audit report has been accepted by CCA who doesn't have any suggestion or comment about it. We are honored to have met Dr. Alexander Lauro who conducted on March 6-9, 2017 the AUDIT in San Marino Salumi Establishment.
Once CCA received the report, immediately informed the establishment as to resolve as soon as possible the identified noncompliances recommending a reassessment of HACCP Plan, particularly:

Identify CCP C1 in accordance to 9 CFR 417.2, (c) (2)
Define clearly the frequencies at which ongoing verification procedures on respecting 9 CFR 417.2 (c) (7)
List specific corrective actions taken in response to deviations, 9 CFR 417.3 (a)

As to ensure the long term measures to meet the regulatory requirements outlined in 9 CFR 417, CCA will be directly informed by the Supervisor through his inspection reports.
Furthermore Vet Service continues to maintain relationship with the Italian Task Force of Inspectors working on export USA through collaboration and training.

Recently the last supervisor report confirms San Marino Salumi establishment has already modified its HACCP program solving the noncompliances above indicated.

Il Responsabile U.O.S Sanità Veterinaria e Igiene Alimentare
Dr. Antonio Rutti

Direttore Dipartimento Prevenzione

ISTITUTO PER LA SICUREZZA SOCIALE · DIPARTIMENTO PREVENZIONE · REP. DI SAN MARINO

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