



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

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Dr. Maurizio Berardi  
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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 April 28 to May 2, 2008. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 690-5646, by facsimile at (202) 720-0676, or electronic mail at [donald.smart@fsis.usda.gov](mailto:donald.smart@fsis.usda.gov).

Sincerely,

Donald Smart  
Director  
International Audit Staff  
Office of International Affairs

Enclosure

FINAL REPORT OF AN AUDIT CARRIED OUT IN SAN  
MARINO COVERING SAN MARINO'S MEAT PRODUCTS  
INSPECTION SYSTEM

APRIL 28 through MAY 2, 2008

Food Safety and Inspection Service  
U.S. Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA/DSP	Central Competent Authority /Dipartimento Di Sanita' Pubblica'
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-to-Eat
<i>Salmonella</i>	<i>Salmonella</i> Species
SSOP	Sanitation Standard Operating Procedures
VS	Veterinary Services

## 1. INTRODUCTION

The audit took place in San Marino from April 28 through May 2, 2008. An opening meeting was held on April 28 in San Marino with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of San Marino's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA.

## 2. OBJECTIVE OF THE AUDIT

This audit was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the processing establishment certified by the CCA as eligible to export meat products to the United States (U.S.).

In pursuit of the objective, the following sites were visited: headquarters of the CCA, one government microbiological and residue laboratory, and a meat processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
Laboratories		1	
Meat Processing Establishments		1	

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with the CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters office. The third part involved an on-site visit to one processing establishment. The fourth part involved a visit to one government microbiology laboratory that conducts ready-to-eat testing (RTE) on samples from the establishment that exports to the U.S.

Program effectiveness determinations of San Marino's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS); (2) animal disease controls; (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs; (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species (*Salmonella*). San Marino's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the auditor evaluated the nature, extent and degree to which findings impacted food safety and public health. The auditor also assessed how

inspection services are carried out by San Marino and determined if establishment and inspection system controls were in place to ensure that the production of meat products are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that San Marino's meat inspection system would be audited against two standards: (1) Food Safety and Inspection Service (FSIS) regulatory requirements; and (2) any equivalence determinations made for San Marino. FSIS requirements include, among other things: daily inspection in the certified establishment; periodic supervisory visits to the certified establishment; the handling and disposal of inedible and condemned materials; sanitation of facilities and equipment; residue testing; species verification; and requirements for HACCP, Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Systems (SPS).

Equivalence determinations are those that have been made by FSIS for San Marino under provisions of the Sanitary/Phytosanitary Agreement. Currently, there are no equivalence determinations for San Marino.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations; in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.);
- The Federal Meat Inspection Regulations (9 CFR, Parts 301 to end), which include the Pathogen Reduction/HACCP (PR/HACCP) regulations.

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS website at the following address:

[http://www.fsis.usda.gov/Regulations\\_&Policies/Foreign\\_Audit\\_Reports/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/Foreign_Audit_Reports/index.asp)

The last two audits of San Marino's food safety system were conducted in 2005 and 2007.

During the 2005 audit, the following deficiencies were noted:

- The pest control program included using rodent bait inside the facility (above the ceiling and in the basement);
- HACCP records for Critical Control Point (CCP) (C1) monitoring did not include the time of monitoring; and
- HACCP records for verification did not include the type of verification performed or the result of the verification.

During the 2007 audit, the following deficiencies were noted:

- During pre-operational sanitation verification in the drying room, meat and fat particles from the previous day's operations were observed on a ready-to-use white plastic apron stored in a utility locker;
- In the ham de-molding room, a leaky and rusty valve was observed on the water conduit of a cooling condenser unit. No exposed product was stored in the vicinity. The establishment officials stated that they would correct the faulty valve immediately;
- Corrective actions were not documented for deviations from critical limits at CCP 3 in the HACCP monitoring record; and
- The establishment did not follow its written procedure for thermometer calibration to re-calibrate the thermometers that exceeded the acceptable range of  $\pm 0.3$  °C on multiple occasions.

## 6. MAIN FINDINGS

### 6.1 Legislation

Decree Number 70, of April 27, 1993, pertaining to the labeling requirements of food from animal origin, has been replaced with Decree Number 55 of April 14, 2008.

### 6.2 Government Oversight

Since the audit of 2005, San Marino's inspection system has undergone internal re-organization. As a result of this re-organization, the Dipartimento Di Sanita' Pubblica' (DSP) has replaced the formerly known Environmental Hygiene Service (EHS). The Sanita Veterinaria e Igiene Alimentare (Veterinary Services) is the component in the DSP which is responsible for the implementation and oversight of inspection within the meat establishments in San Marino and directly reports to the Department of Public Sanitation.

#### 6.2.1 CCA Control Systems

The CCA has control over the entire inspection system and has authority for certifying and decertifying the establishments for export to the U.S. The CCA is responsible for: carrying out inspection activities at the establishment; testing for *Listeria monocytogenes* (*Lm*) and *Salmonella* species on product; and enforcing the U.S. requirements.

#### 6.2.2 Ultimate Control and Supervision

The CCA provides guidelines on the FSIS requirements directly to the inspector at the establishment.

#### 6.2.3 Assignment of Competent, Qualified Inspectors

The auditor observed that a competent, qualified inspector was assigned to the establishment eligible to export to the U.S.

#### 6.2.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and responsibility to enforce Decrees of San Marino pertinent to meat inspection and FSIS requirements.

- One establishment received a Notice of Intent to Delist (NOID) for not meeting some of the FSIS requirements.

#### 6.2.5 Adequate Administrative and Technical Support

- The government microbiological and residue laboratory is not an accredited laboratory.
- Many functions of the operating system of the DSP are aligned with standards prescribed in the "Manuale del Sistema di Gestione per La Qualita' Uni en ISO 9001:2000".

#### 6.2.6 Headquarters Audit

The auditor conducted an audit of inspection system documents at San Marino's headquarters office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports;
- Supervisory visits to establishments that were certified to export to the U.S.;
- Training records for inspectors and laboratory personnel;
- New laws and implementation documents such as: regulations; notices; directives; and guidelines; and
- Sanitation and processing inspection procedures and standards.

No concerns arose as a result of the examination of these documents.

#### 6.3. Audit of Regional and Local Inspection Sites

There are no regional or local inspection sites within the country of San Marino. The headquarters office serves as the only office within the country.

### 7. ESTABLISHMENT AUDITS

The FSIS auditor visited one processing establishment. The establishment received a NOID.

Specific deficiencies are noted in the attached individual establishment review form.

### 8. LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to U.S. requirements.

Residue laboratory audits focus on: sample handling; sampling frequency; timely analysis; data reporting; analytical methodologies; tissue matrices; equipment operation and printouts; detection levels; recovery frequency; percent recoveries; intra-laboratory check samples; and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on: analyst qualifications; sample receipt; timely analysis; analytical methodologies; analytical controls; recording and reporting of results; and check samples. If private laboratories are used to test samples of product destined for export to the U.S., the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following microbiology laboratory which is currently testing products for the U.S. was audited:

Republic of San Marino  
Social Security Institute  
Biological Unit  
Borgo Maggiore, RSM

The following concerns arose as a result of the audit:

- The government microbiological and residue laboratory is not an accredited laboratory;
- A review of the residue program was not within the scope of this audit;
- The laboratory tests cooked ham product for *Salmonella* (MLG 4.04) and *Lm* (MLG 8.06) utilizing FSIS methods listed in the Microbiological Laboratory Guide (MLG); however, records of procedures, e.g., time, temperature, pH, amounts of reagents used, etc., are not maintained; and
- The laboratory is not capable of conducting gene confirmatory tests for *Lm*; however, should the need arise, samples may be sent to laboratories in Italy.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess San Marino's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audit of the establishment, and except as noted below, San Marino's inspection system had controls in place for: SSOP programs; all aspects of facility and equipment sanitation; the prevention of actual or potential instances of product cross-contamination; good personal hygiene practices; and good product handling and storage practices.

In addition, San Marino's inspection system had controls in place for: water potability records; chlorination procedures; back-siphonage prevention; separation of operations; temperature control; work space; ventilation; welfare facilities; and outside premises.

## 9.1 Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met according to the criteria employed in the U.S. domestic inspection program. The SSOP in the establishment audited were found to meet the basic FSIS regulatory requirements with the following deficiencies:

- Beaded condensation was observed over the exposed product in two fresh ham storage coolers;
- A vacuum packing machine used to vacuum pack cooked ham had meat, fat and grease build-up on the pressing slab and other hard-to-clean areas of the machine;
- A ready-to-use work table for product preparation in the cooked product packaging room was observed with meat and fat particles from the previous day's use; and
- During the pre-operational sanitation verification, fat deposits were observed on a ham trimming and boning line around the rim of a perforated stainless steel work surface used for ham trimming.

## 9.2 Sanitation

- In the establishment audited, deficiencies with ventilation were observed.
- In the establishment audited, deficiencies with sanitary operational practices were observed.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring: adequate animal identification; humane handling and humane slaughter; control over condemned and restricted product; and procedures for sanitary handling of returned and reconditioned product. The auditor determined that San Marino's inspection system had adequate controls in place. No deficiencies were noted.

There have been no outbreaks of animal diseases with public health significance since the last FSIS audit.

## 11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

San Marino is not required to implement procedures for anti-mortem and post-mortem inspection of raw material obtained from certified establishments and used in the preparation of meat products for export to the U.S.

The controls also include the implementation of HACCP systems in all establishments and the implementation of a generic *E. coli* testing program in slaughter establishments. The requirements for development and implementation of a generic *E. coli* testing program are not applicable to San Marino.

The following concerns arose as a result of the audit:

- In the establishment audited, the appropriate critical limit was not being monitored and documented; and
- In the establishment audited, corrective actions were not documented when deficiencies were observed during ongoing verification of instrument calibration.

#### 11.1 Humane Handling and Slaughter

There are no slaughter establishments certified to export to the U.S. Currently, San Marino receives its raw product that is used to prepare product for export to the U.S. from certified establishments in Italy.

#### 11.2 Hazard Analysis and Critical Control Point (HACCP) Implementation

All establishments approved to export meat products to the U.S. are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the U.S. domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the establishment. The establishment had adequately implemented the HACCP requirements, except as noted below:

- The appropriate critical limit was not being monitored and documented; and
- The corrective actions were not documented when deficiencies were observed during on-going verification of instrument calibration.

#### 11.3 Testing for Generic *Escherichia coli* (*E. coli*)

Testing for generic *E. coli* is not applicable.

#### 11.4 Testing for *Listeria monocytogenes* (*Lm*)

The only certified establishment audited was producing ready-to-eat (RTE) products for export to the U.S.

No concerns arose as a result of the audit.

### 12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include: sample handling and frequency; timely analysis; data reporting;

tissue matrices for analysis; equipment operation and printouts; minimum detection levels; recovery frequency; percent recoveries; and corrective actions.

- Residue testing was not required by San Marino as all raw materials were obtained from Italy. Applicable residue testing is conducted by Italy.

### 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

#### 13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the establishment audited.

#### 13.2 Testing for *Salmonella* Species

The establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for *Salmonella* was properly conducted in the establishment audited.

#### 13.3 Species Verification

Only one species (pork) is processed at the establishment.

#### 13.4 Periodic Reviews

During this audit, it was found that, in the establishment audited, periodic supervisory reviews were being performed and documented as required.

#### 13.5 Inspection System Controls

Inspection controls were in place for importation of only U.S.-eligible livestock from other countries, i.e., only from U.S.-eligible third countries, U.S.-certified establishments within those countries and the importation of only U.S.-eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for: security items; shipment security; and products entering the establishments from outside sources.

#### 14. CLOSING MEETING

A closing meeting was held on May 2 in San Marino with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Alam Khan, DVM  
Senior Program Auditor



#### 15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms  
Individual Foreign Laboratory Reports  
Foreign Country Response to Draft Final Audit Report (when it becomes available)

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION San Marino Salumi Strada del Lavoro, 45	2. AUDIT DATE 04/29/08	3. ESTABLISHMENT NO. 2L	4. NAME OF COUNTRY San Marino
5. NAME OF AUDITOR(S) Alam R. 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.	X	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	
<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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. NOID	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 04/29/08 Est #: 2L (San Marino Salumi [P]) (. San Marino)

The following observations were made during the pre-operational sanitation verification.

- 10 a) A vacuum packing machine used to vacuum pack cooked ham had meat, fat and grease build up on the pressing slab and other hard to clean areas of the machine. The inspector in-charge rejected the vacuum package machine.  
 b) A ready-to-use work table for product preparation in the cooked product packaging room was observed with meat and fat particles from the previous day's use. The veterinarian in-charge rejected the table.  
 c) Fat deposits were observed around the rim of a perforation located in the center of a stainless steel work area for ham trimming on the ham trimming line. The area was thoroughly cleaned and sanitized while the auditor was still in the trimming line.

The following was observed during operational sanitation verification.

Beaded condensation was observed over the exposed product in two fresh ham storage coolers during operational sanitation verification. The product was retained by the veterinarian in-charge. [Regulatory reference: 9 CFR 416.13 (a-c)]

- 16/ 51 The established critical limit of 150 ppm at CCP (C1), was not being monitored, instead a number derived from a formula used in the calculation of ppm and that is irrelevant to monitoring of critical limit, was documented in the daily monitoring record. [Regulatory reference: 9 CFR 417.2 (c) (6) & 417. 5(a) (3)13 (a-c)]
- 19/51 The record for ongoing verification of calibration of thermometer indicated a couple of entries exceeding the acceptance range of  $\pm 0.7^{\circ}\text{C}$ . No document to support that correction of the non compliant thermometer took place, was presented for the review. [Regulatory reference: 9 CFR 417.4 (a)(2) & 417.5 (a)(3)]
- 41/51 Dripping condensation was observed in more than one production room on the air ducts and/or on the condenser units. No exposed product was stored under the condensation. The veterinarian in-charge gave assurance that the problem will be corrected as soon as possible. [Regulatory reference: 9 CFR 416.2 (d)]
- 46/51 a) The conveyor belts for moving finished and or/ un-finished products in several production rooms were observed to be frayed or cracked. This condition may prevent thorough cleaning and consequently may form bio-film on the cratered surfaces of the belt. [Regulatory reference 9CFR 416.4 (a)]  
 b) Cobwebs were observed on the roll up door separating a vestibule of the receiving dock and and the raw material receiving room. [Regulatory reference 9CFR 416.4 (b)]
- 58 The Government officials accompanying the auditor issued an NOID to the establishment for the SSOP and SPS deficiencies identified during the audit.

61. NAME OF AUDITOR  
 Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

*Alam R. Khan* 8/4/08

**Smart, Donald**

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**From:** Dott. Maurizio Berardi [maurizio.berardi@iss.sm]  
**Sent:** Monday, August 25, 2008 7:13 AM  
**To:** Smart, Donald  
**Cc:** Biasetti, Dana  
**Subject:** San Marino Report

Dear Donald Smart

We received your copy of the draft final audit report.  
**No comment to do.**

Kind regards

Maurizio Berardi

8/25/2008