



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Maurizio Berardi
Chief Veterinary Officer
Veterinary Services
Istituto Sicurezza Sociale
Via La Toscana
1-47893 Borgo Maggiore
Republic of San Marino

JUL - 3 2007

Dear Dr. Berardi:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in San Marino from March 21 to March 26. San Marino did not provide any comments in response to the draft final report. Enclosed is a copy of the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

by Manjiv H. Chaudry
Donald Smart

Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

JUN 19 2007

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

March 21 – 26, 2007

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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
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<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 March 21, 2007 through March 26, 2007.

An opening meeting was held on March 21, 2007 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, the Dipartimento Di Sanita Pubblica.

2. OBJECTIVE OF THE AUDIT

This audit was the 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.

In pursuit of the objective, the following sites were visited: headquarters of the CCA and a meat processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
Laboratories		0	
Meat Processing Establishments		1	

3. PROTOCOL

This on-site audit was conducted in three 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.

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 Critical Control Point (HACCP) programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *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 the production of meat products that 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) FSIS regulatory requirements and (2) any equivalence determinations made for San Marino. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, SPS and testing for generic *E. coli* and *Salmonella*.

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 with San Marino.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States 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 regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&Policies/Foreign_Audit_Reports/index.asp

The last two FSIS audits of San Marino's food safety system were conducted in 2001 and 2005.

The FSIS audit of 2001 was an initial audit. During the 2001 FSIS audit, it was determined that:

- EHS/VS was not monitoring/ verifying adequacy and effectiveness of SSOP and HACCP
- In-plant veterinarians were not trained in FSIS' pathogen reduction and HACCP requirements.
- San Marino was not providing daily inspection.
- San Marino was not conducting monthly supervisory reviews.
- San Marino was not using the appropriate methodology for testing ready-to-eat products; San Marino's follow-up actions to a positive *Listeria monocytogenes* sample were not equivalent to FSIS' follow-up actions.

During the 2005 FSIS audit, the following deficiencies were noted:

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

6. MAIN FINDINGS

6.1 Legislation

No new information on legislation was provided to the auditor on this audit.

6.2 Government Oversight

Since the last FSIS audit of 2005, San Marino's inspection had undergone internal reorganization. As a result of this reorganization, the former Department of Health and Social Security is now referred to as the Department of Public Sanitation. The Veterinary Services which is responsible for the implementation and oversight of inspection within the meat establishments in San Marino now 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 establishments for export to the United States. The CCA is responsible for carrying out inspections of individual establishments; testing for *Listeria monocytogenes* and *Salmonella* species on product, and its verification.

6.2.2 Ultimate Control and Supervision

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 United States.

6.2.4 Authority and Responsibility to Enforce the Laws

No deficiencies were noted in this category.

6.2.5 Adequate Administrative and Technical Support

The CCA does not have the resources or capabilities to conduct audits of its government-owned and operated laboratory; however, it is currently conducting negotiations with third-party experts to have audits conducted.

6.3 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 United States.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation and processing inspection procedures and standards.

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

6.3.1 Audit of Regional and Local Inspection Sites

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited one processing establishment. The establishment was not delisted and did not receive a Notice of Intent to Delist (NOID).

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

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States 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 United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratory is currently testing products for the United States:

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

The laboratory was not selected for this audit.

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 SSOP

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

- In the drying room, during pre-operational sanitation verification, 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.

9.2 Sanitation

In the ham de-moulding 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.

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.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

No deficiencies were noted.

11.1 Humane Handling and Slaughter

No San Marino slaughter facilities are certified as eligible to export to the U. S. at this time.

11.2 HACCP Implementation.

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

The HACCP programs were reviewed during the on-site audit of the one establishment. This establishment, and except as noted below, had adequately implemented the HACCP requirements.

- Corrective actions were not documented for deviations from critical limits at CCP 3 in the HACCP monitoring record.
- The establishment did not follow its written procedure for thermometer calibration to re-calibrate the thermometers that exceeded the acceptable range of ± 0.3 °C on multiple occasions.

11.3 Testing for Generic *E. coli*

San Marino receives the product for processing from approved establishments in other countries so testing for generic *E. coli* is not applicable.

11.4 Testing for *Listeria monocytogenes*

The only certified establishment audited was producing ready-to-eat products for export to the United States. In accordance with United States requirements, the HACCP plans in this establishment had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

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 controls are not applicable as San Marino receives the product for processing from approved establishments in other countries

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 all processing establishments.

13.2 Testing for *Salmonella* in Raw Product

No San Marino slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, the establishment was not required to meet the FSIS regulatory requirements for *Salmonella* testing of raw product.

13.3 Species Verification

Species verification was being conducted in the establishment audited.

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

The CCA had controls in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only 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 March 26, 2007 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

A handwritten signature in black ink, appearing to read "Alam Khan DVM". The signature is written in a cursive style with a large, looping initial "A".

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION San Marino Salumi s.r.l Strada del Lavoro, 45 GUALDICCIOLO Republica San Marino	2. AUDIT DATE 03/22/2007	3. ESTABLISHMENT NO. 2L	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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	
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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		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.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		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
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

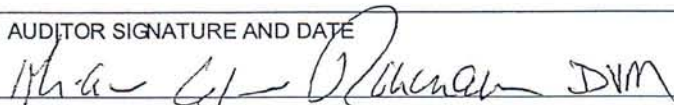
Date: 03/22/2007 Est #: 2L (San Marino Salumi [P]) (San Marino)

- 10 In the drying room, during pre-operational sanitation verification, 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. [Regulatory reference: 9CFR416.13(c)] The establishment took immediate corrective action.
- 16/51 Corrective actions were not documented for deviations from critical limits at CCP 3 in the HACCP monitoring record. Establishment officials indicated they would use a new HACCP plan exclusively designed for U.S. export product when it begins exporting. [9CFR 417.5(a)(3), 417.8 (h)]
- 20/51 The establishment did not follow its written procedure for thermometer calibration to re-calibrate the thermometers that exceeded the acceptable range of ± 0.3 °C on multiple occasions. The official veterinarian leading the audit gave assurances that the problem would be immediately corrected. [9CFR 417.4(a)(2), 417.8(c) and (h)]
- 39/51 In the ham de-moulding 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. Establishment officials stated they would correct the faulty valve immediately. [9 CFR 416.2(b)]

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Alam Khan, DVM, with the initials "DVM" written to the right of the signature.

From: Dott. Maurizio Berardi [mailto:maurizio.berardi@iss.sm]

Sent: Wednesday, June 06, 2007 5:46 AM

To: Smart, Donald

Subject:

Dear Donald Smart

We received your copy of the draft final audit report.

No comment to do.

Only one correction and one doubt.

The correction regards page 8 point 8., the correct diction of the labortory is:

Republic of San Marino

Social Security Institute

Department of Public Sanitation (not Enviromental Hygine Service), Biological Unit

Borgo Maggiore RSM

The doubts regards page 10, point 13. ENFORCEMENTS CONTROLS.

What means "The CCA was not enforcing some of FSIS's requirements for *Salmonella*

Kind regards

Maurizio Berardi