



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Don
5/25/06

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

MAY 10 2006

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 December 12 through December 16, 2005. 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, please contact me at 202-720-3781, facsimile 202-690-4040, or e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Geoffrey Wiggin, Minister-Counselor, US Embassy, Rome

Barbara Masters, Administrator, FSIS

Scott Bleggi, FAS Area Officer

Robert Macke, ITP, FAS

Karen Stuck, Assistant Administrator, OIA

William James, Deputy Asst. Administrator, OIA

Donald Smart, Director, Review Staff, OPEER

Sally White, Director, IES, OIA

Clark Danford, Director, IEPS, OIA

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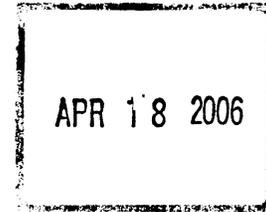
Linda Swacina, Executive Director, FSIA

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Nancy Goodwin, IES, OIA

Country File

FINAL



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

DECEMBER 12 – 16, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA/EHS	Central Competent Authority /Environmental Hygiene Service
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
VS	Veterinary Services

1. INTRODUCTION

The audit took place in San Marino from December 12 through December 16, 2005. An opening meeting was held on December 12, 2005 in San Marino, with the Central Competent Authority (CCA), Environmental Hygiene Service. 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 the first routine audit of San Marino since it gained eligibility to export meat products to the United States. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the processing establishment that will be certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one laboratory performing analytical testing on United States-destined product, and one meat processing establishment.

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

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with 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. The third part involved an on-site visit to one processing establishment. The fourth part involved a visit to one government laboratory. The Department of Health and Social Security, Environmental Hygiene Service, Biological Unit, was conducting analyses of field samples for the presence of *Listeria monocytogenes* and *Salmonella*. A residue laboratory was not audited since San Marino is receiving raw product from other countries.

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 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, monthly 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, 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 for 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 only previous audit was the initial equivalence audit conducted in 2001. During that audit, it was determined that EHS/VS:

- was not monitoring/verifying the adequacy and effectiveness of SSOP and HACCP plans,
- 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.

5. MAIN FINDINGS

6.1 Government Oversight

The Department of Health and Social Security is the department responsible for all issues that involve public health. The Environmental Hygiene Service is an agency within the Department of Health and Social Security that oversees Veterinary Services. Veterinary Services is directly responsible for the implementation and oversight of inspection of the meat establishments in San Marino.

6.1.1 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. The CCA is responsible for carrying out testing for *Listeria monocytogenes* and *Salmonella* on ready to eat product, and all verification activities.

6.1.2 Ultimate Control and Supervision

The FSIS auditor verified that the EHS has ultimate control and supervision of the inspection program.

6.1.3 Assignment of Competent, Qualified Inspectors

The auditor observed that competent, qualified inspectors were assigned to the establishment that will be eligible to export to the United States.

6.1.4 Authority and Responsibility to Enforce the Laws

The Environmental Hygiene Service has the authority and responsibility to enforce the laws.

6.1.5 Adequate Administrative and Technical Support

San Marino has adequate administrative and technical support to operate its inspection program.

5.1 Headquarters Audit

The auditor conducted a review 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 will be 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, slaughter 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 headquarters' office serves as the only inspection office within the country.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited one processing establishment. The establishment was not delisted by San Marino and did not receive a Notice of Intent to Delist.

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.

The following laboratory was reviewed:

- Environmental Hygiene Service, Biological Unit in Borgo Maggiore

No deficiencies were noted.

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 audits of establishments, 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, ante-mortem facilities, welfare facilities, and outside premises.

8.0 SSOP

The processing 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 was found to meet the basic FSIS regulatory requirements, with the following deficiency.

- Corrective actions for SSOP non-compliances did not include preventive actions.

9.2 Sanitation

No deficiencies were noted.

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.

11.1 Humane Handling and Slaughter

Not applicable.

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. The program in the one processing establishment was evaluated according to the criteria employed in the United States' domestic inspection program.

This establishment had adequately implemented the HACCP requirements with the exception of the following deficiencies:

- 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.

11.3 Testing for Generic *E. coli*

Because the establishment is a processing establishment only, testing for generic *E. coli* is not required. Generic *E. coli* testing is performed in the country of origin.

10.3 Testing for *Listeria monocytogenes*

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

11. 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 is not applicable. San Marino receives the product for processing from eligible establishments in other countries. Residue testing is performed in the country of origin.

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 processing establishment.

13.2 Testing for *Salmonella* in Raw Product

Because the establishment is a processing establishment only, testing for *Salmonella* in raw product is not required. *Salmonella* testing is performed in the country of origin.

13.3 Species Verification

Species verification was being conducted as required.

13.4 Monthly Reviews

Monthly supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

Inspection controls were 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.

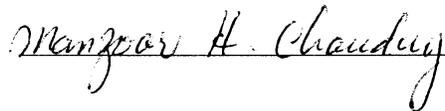
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on December 16, 2005 in San Marino with the CCA. At this meeting, the primary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

 Royce E. Sperry
Deputy Director, OPEER/PRS

 Manjiv H. Chaudhry

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report *(no comments received)*

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION San Marino Salumi s.r.l. Strada del Lavoro, 45 Gualdicciolo, San Marino	2. AUDIT DATE 12/14/05	3. ESTABLISHMENT NO. 2L	4. NAME OF COUNTRY San Marino
	5. NAME OF AUDITOR(S) Royce E. Sperry		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.			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.		X	38. Establishment Grounds and Pest Control		X
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
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.			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.			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.		X	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		
24. Labeling - Net Weights			52. Humane Handling		
25. General Labeling			53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection		
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		
27. Written Procedures			Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis			56. European Community Directives		
29. Records			57. Monthly Review		
Salmonella Performance Standards - Basic Requirements			58.		
30. Corrective Actions			59.		
31. Reassessment					
32. Written Assurance					

60. Observation of the Establishment

Est. #: 2L
San Marino Salumi
Gualdicciolo, SM

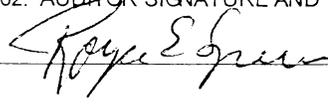
December 14, 2005

- 12 Corrective action for SSOP non-compliances did not include preventive action. 9 CFR 416.15
- 22 HACCP record for CCP (C1) monitoring did not include the time of monitoring.
HACCP records for verification do not include the type of verification performed or the result of the verification. 9 CFR 417.5.a.3
- 38 The pest control program includes using poison inside of the facility (above the ceiling and in the basement). 9 CFR 416.2.a Establishment proposed an immediate corrective action to remove the poison from the plant. SM inspection will verify that the immediate corrective action was implemented.

61. NAME OF AUDITOR

Rovce E. Sperry

62. AUDITOR SIGNATURE AND DATE



12/23/05