



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250



Dr. Silvio Borrello
General Director
Ministry of Health
Directorate General for Veterinary Health and Food
Via Giorgio Ribotta, 5
00144 Rome, Italy

Dear Dr. Borrello:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Italy's meat inspection system March 26 through April 24, 2008. Comments on the draft final report received from the government of Italy have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

bv *Don Carlson, acting Director*

For
Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
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FEB 10 2009

MEMORANDUM

TO: James Dever, Minister-Counselor
US Embassy, Rome
Via Veneto 119/A 00187
Rome, Italy

FROM: Manzoor Chaudry
Deputy Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR ITALY

Dear Mr. Dever,

Please deliver the attached final audit report to Dr. Silvio Borrello, General Director, Ministry of Health, Directorate General for Veterinary Health and Food. Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

by Don Carlson, Acting Director

For Manzoor Chaudry

cc list:

James Dever, Minister-Counselor, US Embassy, Rome
Maria Trinchieri, Commercial Attaché, Embassy of Italy
Canice Nolan, First Secretary, EU Mission to the US, Washington
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Italy Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Italy
FINAL AUDIT LETTER February 9, 2009

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

MARCH 26 THROUGH APRIL 24, 2008

**Food Safety and Inspection Service
United States Department of Agriculture**

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points Systems
<i>Lm</i>	<i>Listeria monocytogenes</i>
MOH	Ministry of Health
NOID	Notice of Intent to Delist
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedure(s)
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Italy from March 26 through April 24, 2008.

An opening meeting was held on March 26 in Rome 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 Italy's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Ministry of Health.

2. OBJECTIVE OF THE AUDIT

This was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments 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, three regional inspection offices, three local inspection offices, one government microbiology laboratory performing analytical testing on United States-eligible product, two pork slaughter establishments, and nine pork processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Rome
	Regional	3	Tuscany, Lombardy, Emilia Romagna
	Local	3	Siena, Como, Parma
Laboratories		1	IZS Pordenone
Meat Slaughter Establishments		2	
Processing Establishments		9	

3. PROTOCOL

This on-site audit was conducted in four parts. The first part included interviews with CCA officials to discuss oversight programs and practices including enforcement activities. The second part involved visits to three regional offices and three local government offices. The third part included on-site visits to 11 establishments: two slaughter establishments, and nine processing establishments. The final part involved the audit of a government laboratory, the Istituto Zooprofilattico Sperimentale (IZS) in Pordenone, which conducts microbiological analyses of field samples for establishments certified to export meat products to the United States.

Program effectiveness determinations of Italy'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 Points (HACCP) programs, (4) residue controls, and (5) enforcement controls. Italy's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Italy 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.

During the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the Food Safety and Inspection Service (FSIS) auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS's requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Italy under provisions of the Sanitary/Phytosanitary Agreement. Alternate procedures have been recognized as equivalent:

1. Government laboratories use ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella*.
2. The use of five 75-gram samples for testing of Ready-To-Eat (RTE) product for *Salmonella*.

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.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of β -agonists"

5. SUMMARY OF PREVIOUS AUDITS

Italy 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 audits of Italy's meat inspection system were conducted in November/December 2005 and March 2007.

During the audit of Italy, conducted by FSIS in November/December 2005, the following deficiencies were identified:

- One establishment was issued a Notice of Intent to Delist (NOID) by the Ministry of Health (MOH) because of SSOP and SPS deficiencies.
- In six establishments, the Ministry of Health was not adequately enforcing FSIS inspection requirements.
- In five of the 13 establishments, the implementation of the SSOP was insufficient to prevent product contamination from occurring.
- In two of 13 establishments, general deficiencies concerning sanitary operations were observed.
- In two of 13 establishments, deficiencies in establishment grounds and pest control were observed.

During the audit of Italy, conducted by FSIS in February/March 2007, the following deficiencies were identified:

- The CCA's internal audit program did not adequately identify/correct the Region's failure to enforce inspection requirements at the establishment level.
- One establishment was delisted and one was issued an NOID by the MOH because of SSOP and SPS deficiencies.
- In two of eight establishments, the implementation of the SSOP was insufficient to prevent product contamination from occurring.
- In five of eight establishments, preventive measures were not included as part of SSOP corrective actions.

- In three of eight establishments, general deficiencies concerning sanitary operations were observed.
- In two of eight establishments, deficiencies in establishment grounds and pest control were observed.
- In one of eight establishments, deficiencies concerning maintenance of equipment and utensils were noted.
- In six of eight establishments, deficiencies concerning construction and maintenance were noted.
- In four of eight establishments, deficiencies were identified regarding the verification and/or validation of the HACCP plan.
- In three of eight establishments, preventive measures were not recorded when deviations from critical limits occurred.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Italy's legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

At the highest level, oversight of Italy's meat inspection system is provided by the Department of Veterinary Public Health, Nutrition, and Food Safety (DVPHNFD), which is one of four departments under the MOH. The DVPHNFD is further divided into three branches which includes two General Directorates, and the office of the Secretariat responsible for food-related risk assessment. Of the two General Directorates, the General Directorate for Food Safety and Nutrition (DGSAN) is the entity which is predominantly responsible for the enforcement those requirements which are of interest to FSIS. This General Directorate provides oversight to nine offices addressing products of animal hygiene and export of food products.

The ultimate control of establishment certified to export to the United States is achieved through concerted oversight provided by the CCA, regional and provincial offices, and local health units, or "Azienda Sanitara Locale" (ASL). Each region and province in Italy has a Directorate or an equivalent public sanitation authority which oversees a varying number of ASLs in the area. The establishments certified to export to the US are regulated these local health units, and the assigned veterinarians (designated as official veterinarians) are paid directly by the ASL.

6.2.2 Ultimate Control and Supervision

The CCA has ultimate control over all establishments certified for export to the United States. The CCA has the ultimate control over all government laboratories.

6.2.3 Assignment of Competent, Qualified Inspectors

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

6.2.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and the responsibility to enforce U.S. and E.C. requirements.

6.2.5 Adequate Administrative and Technical Support

The CCA has adequate administrative and technical support.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters, regional and local offices, and in-plant inspection offices of the audited establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports,
- Training records for inspectors and laboratory personnel,
- Animal disease status,
- Supervisory visits to U.S. certified establishments,
- New laws and implementation documents such as regulations, notices, directives and guidelines,
- Official communications with field personnel, both in-plant and supervisory, in U.S. certified establishments,
- Sampling and laboratory analyses for residues,
- Sanitation, and slaughter inspection procedures and standards,
- Species verification policy,
- Enforcement actions.

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

6.3.1 Audits of Regional and Local Inspection Sites

Three regional offices (Tuscany, Lombardy, and Emilia Romagna) and three local offices (Siena, Como, and Parma) were audited.

- During a review of documents and procedures at the Regional offices, it was noted that internal reviews did not adequately identify/correct failures to enforce inspection requirements.

7. ESTABLISHMENT AUDITS

The FSIS auditor audited a total of eleven facilities, including two pork slaughter and nine pork processing establishments. Of the eleven establishments audited, two were delisted, and one received a NOID. The specific deficiencies are noted on the attached individual establishment reports.

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, and intra-laboratory check sample 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 sample programs.

A government laboratory conducting microbiological analyses of field samples, the Istituto Zooprofilattico Sperimentale in Pordenone, was audited. No concerns arose as a result of this audit.

While a review of a residue laboratory was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, regional, and local inspection offices. No deficiencies were noted, and Italy's National Residue Testing Plan for 2008 was being followed and was on schedule.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess an exporting country'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, except as noted below, Italy'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, except as noted below, Italy's inspection system had controls in place for lighting, plumbing and sewage, water supply, dressing rooms/lavatories, and condemned product control.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for the SSOP were being met, according to the criteria employed in the United States' domestic inspection program.

In four of the eleven establishments audited, deficiencies involving the implementation of the establishment's SSOP were identified:

- In two establishments, SSOP deficiencies were observed during pre-operational sanitation verification.
- Beaded condensate was observed above exposed product in two establishments.

9.2 SANITATION PERFORMANCE STANDARDS

SPS requirements were not met in nine of the eleven establishments audited, in that the following deficiencies were identified:

- In four of the eleven establishments audited, grounds about the establishments were not maintained to prevent conditions that could lead to insanitary conditions.
- In five of the eleven establishments audited, deficiencies with the establishment's construction and maintenance were observed.
- In one of the eleven establishments audited, deficiencies with the adequate ventilation were observed.
- In one of the eleven establishments audited, dressing rooms/lavatories were not maintained in sanitary condition.
- In two of the eleven establishments audited, deficiencies with the equipment and utensils were observed.
- In eight of the eleven establishments audited, deficiencies with sanitary operational practices were observed.

9.3 EC Directive 64/433

In nine of the 11 establishments audited, EC Directive 64/433 requirements related to sanitation controls were not met. Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

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

There had 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 dispositions; humane handling and humane slaughter; post-mortem inspection procedures and dispositions; 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 testing program for generic *E. coli* in slaughter establishments.

- In two of the eleven establishments audited, deficiencies concerning the labeling of product/ingredients were identified.

11.1 Humane Handling and Humane Slaughter

Special emphasis was placed on verification of humane handling and slaughter of livestock.

No deficiencies were observed.

11.2 HACCP Implementation

No deficiencies were observed.

11.3 Testing for Generic *E. coli*

No deficiencies were observed.

11.4 Testing for *Listeria monocytogenes*

No deficiencies were observed.

11.5 EC Directive 64/433

Those provisions of EC Directive 64/433 related to slaughter controls were effectively implemented at the eleven establishments audited.

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

The audit of a residue lab was not within the scope of this audit.

Italy's National Residue Control Program for 2007 was being followed and was on schedule.

12.1 EC Directive 96/22

While a review of a residue laboratory was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, regional, and local inspection offices. No deficiencies were noted.

12.2 EC Directive 96/23

While a review of a residue laboratory was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, regional, and local inspection offices. No deficiencies were noted.

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* species.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily, and was well-documented, at all eleven establishments audited.

13.2 Testing for *Salmonella* Species

Two slaughter establishments audited were required to test for *Salmonella* in raw product. No deficiencies were observed regarding the testing programs for *Salmonella* species.

13.3 Species Verification

At the time of this audit, Italy was not required to test product for species verification.

13.4 Periodic Reviews

Although periodic reviews were conducted by the Regions and the CCA, many items related to EU and FSIS requirements were not adequately identified/corrected.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between the United States with product intended for the domestic market.

In addition, 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.

- However, deficiencies involving the enforcement of FSIS requirements were identified at nine of the 11 establishments visited.

14. CLOSING MEETING

A closing meeting was held on April 24, 2008, in Rome with the CCA. At this meeting, the preliminary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

For Dr. Alam R. Khan
Senior Program Auditor

by Don Carlson, DVM

15. ATTACHMENT

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 Alcisa S.p.A. Via Roma -73 40069 Zola Predosa (BO)	2. AUDIT DATE 04/10/2008	3. ESTABLISHMENT NO. 41L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Aiam 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	
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	
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	X
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.		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	
25. General Labeling	X	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	X
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

Date: 04/10/2008 Est #: 41L (Alcisa S.p.A. []) (Predosa, Italy)

- 10 Beaded condensate was observed on overhead plumbing above exposed product at more than one place in Salami drying room three and four. The surfaces directly under the condensate were wet indicating the dripping of the condensate onto the product. The official veterinarian took control of the product. [Regulatory reference: 9CFR 416.13 (a)-(c)]
- 25 In one of the processing room, two buckets had unlabeled liquid in them. The official veterinarian requested immediate corrective action. [Regulatory reference: 9CFR 318.1(c)]
- 46/51/56 In the freezer, the frozen mortadella was stacked underneath a container that had rusty supports and mesh that was posing potential contamination of mortadella from the falling rust when shifting the containers. The deficiency was corrected immediately by the establishment. [9CFR 416.4 (b)] [EC Directive 64/433]

61. NAME OF AUDITOR

Alan R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

H. Munzoor H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Greci Enzo S.p.A Via Calestano, 38/A 43035 Felino (PR)	2. AUDIT DATE 4/18/08	3. ESTABLISHMENT NO. 144L	4. NAME OF COUNTRY Italy
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)		Audit Results	Part D - Continued Economic Sampling	Audit Results
Basic Requirements			33. Scheduled Sample	
7. Written SSOP			34. Species Testing	
8. Records documenting implementation.			35. Residue	
9. Signed and dated SSOP, by on-site or overall authority.			Part E - Other Requirements	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			36. Export	
10. Implementation of SSOP's, including monitoring of implementation.			37. Import	
11. Maintenance and evaluation of the effectiveness of SSOP's.			38. Establishment Grounds and Pest Control	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			39. Establishment Construction/Maintenance	
13. Daily records document item 10, 11 and 12 above.			40. Light	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			41. Ventilation	
14. Developed and implemented a written HACCP plan.			42. Plumbing and Sewage	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			43. Water Supply	
16. Records documenting implementation and monitoring of the HACCP plan.			44. Dressing Rooms/Lavatories	
17. The HACCP plan is signed and dated by the responsible establishment individual.			45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46. Sanitary Operations	
18. Monitoring of HACCP plan.			47. Employee Hygiene	
19. Verification and validation of HACCP plan.			48. Condemned Product Control	
20. Corrective action written in HACCP plan.			Part F - Inspection Requirements	
21. Reassessed adequacy of the HACCP plan.			49. Government Staffing	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			50. Daily Inspection Coverage	
Part C - Economic / Wholesomeness			51. Enforcement	
23. Labeling - Product Standards			52. Humane Handling	O
24. Labeling - Net Weights			53. Animal Identification	O
25. General Labeling			54. Ante Mortem Inspection	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			55. Post Mortem Inspection	O
Part D - Sampling Generic E. coli Testing			Part G - Other Regulatory Oversight Requirements	
27. Written Procedures		O	56. European Community Directives	
28. Sample Collection/Analysis		O	57. Monthly Review	
29. Records		O	58.	
Salmonella Performance Standards - Basic Requirements			59.	
30. Corrective Actions		O		
31. Reassessment		O		
32. Written Assurance		O		

60. Observation of the Establishment

Date: 4/18/08 Est #: 144L (Greci Enzo S.p.A [P]) (Felino, Italy)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE
Dr Mangor H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Wuber S.p.A. Via F. Beretta, 5 24030 Medolago. (BG)	2. AUDIT DATE 04/11/2008	3. ESTABLISHMENT NO. 368L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Ajam 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	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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.		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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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.		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	X
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: 04/11/2008 Est #: 368L (Wuber S.p.A. [P]) (Medolago, Italy)

- 10 The following observations were made during the pre-operational sanitation verification of the establishment:
- a) In the cooler # 4, one stainless steel bin, that was ready to use, had residues from the previous day's operation.. [Regulatory reference: 9CFR 416.13 (a)(c)]
 - b) The long rectangular moulds that were stacked on the cart in the molding room had gross fat and meat residues from the previous day's operation. The cart was rejected by the official veterinarian. [Regulatory reference: 9CFR 416.13 (a)(c)]

41/51/56 Condensation and a heavy build up of ice around a condenser unit were observed in chiller # 7; wrapped product was stored underneath the condensation. [Regulatory reference: 9CFR 416.2 (d)] [EC Directive 64/433]

45/51/56 In the cooler # 4, the bottom of a metal bin was cracked in two places posing potential for a bio-film formation. The establishment took immediate corrective action. [Regulatory reference: 9CFR 416.3] [EC Directive 64/433]

46/51/56 The under side of the shelf of a sacking rack collected debris and greasy material causing insanitary conditions and potentials for cross contamination [Regulatory reference: CFR 416.4(b)] [EC Directive 64/433, Chapter III (3)]

All deficiencies that had resulted in issuance of an NOID during the last FSIS audit have been addressed and corrected.

61. NAME OF AUDITOR

Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

Dr. Manzoor H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Prosciuttificio Rovagnati SRL Via San Vitale, 29 43030 Sala Baganza Sala Baganza (PR)	2. AUDIT DATE 04/17/2008	3. ESTABLISHMENT NO. 587L	4. NAME OF COUNTRY Italy
	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	
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.		38. Establishment Grounds and Pest Control	
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.	X	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	X
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.		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	X
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: 04/17/2008 Est #: 587L (Prosciuttificio Rovagnati SRL [P]) (Sala Baganza, Italy)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

for Manzoor H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Martelli F.LLi s.p.A Industria Macellazione Via Cantone 22/24 Dosolo, Mantova 46030	2. AUDIT DATE 04/14/2008	3. ESTABLISHMENT NO. 643MSL	4. NAME OF COUNTRY Italy	5. NAME OF AUDITOR(S) Alan R. Khan, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT
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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	X
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.		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	X
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.		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	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park 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	X
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

Date: 04/14/2008 Est #: 643MSL (Martelli F.Li s.p.A [S/P/CS]) (Dosolo, Italy)

10/51/56 Employee's and inspector's aprons were contacting forelimbs of carcasses. There was no facility to wash the apron if they became contaminated. The establishment gave assurance to provide apron washing stations in the evisceration room. [Regulatory references for items a-d: 9CFR 416.4 (a)(b) & 416.13] [EC Directive 64/433, items a-c]

38/51/56 The grounds encompassing the premises were littered with large pieces of scrap meat, equipment, plastic containers, papers, and wooden pallets. Two large open containers of grease were also observed stored near the usable equipment. This presented insanitary conditions and potential harborage for pest. The inspection officials took immediate control action. [Regulatory references: 9CFR 416.2 (a)] [EC Directive 64/433]

39/51/56 a) Flaking paint was observed on the walls near the door in several fresh meat coolers.
b) The fresh belly/back fat cooler floor had several shallow pits that collected a mixture of water and blood preventing effective cleaning of the cooler. The inspection officials took immediate control action. [Regulatory references: 9CFR 416.2 (b)] [EC Directive 64/433]

46/51/56 a) In the equipment washing room cobwebs were found under the air circulation unit. The recently cleaned and ready-to-use equipment was stored underneath this area.
b) A corner of the inedible room, not physically separated from other areas, had a rusty condenser unit and was littered with plastic and paper. A trash container that had dried fecal/ingesta adhered around the lid was stored near the condenser.
c) In one freezer exposed product was present and touching the wall. In another freezer the product was stacked close to the wall and impeded the inspection process.
The inspection officials took immediate control action. [Regulatory references for items a-d: 9CFR 416.4 (a)(b)] [EC Directive 64/433, items a-c]

All deficiencies that had resulted in the delistment of the establishment from the certified list of exporting establishments in Italy during the last FSIS audit have been addressed and corrected.

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

Dr. Mangoor H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Salumificio Piacenti S.r.L. Via del Ponte, 4 - Loc. Canonica 530337 San Gimignano (SI) San Gimignano, Italy	2. AUDIT DATE 03/31/08	3. ESTABLISHMENT NO. 718L	4. NAME OF COUNTRY Italy
	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	
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	X
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.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
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.		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	X	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	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59. Delisment	1
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 03/31/08 Est #: 718L (Salumificio Piacenti S.r.L. [P]) (San Gimignano, Italy)

- 10 a) In Salami Cooling Rooms # 1, 2, 3 and 4 cobwebs, dirt, and debris were observed on walls, electrical boxes, ceilings, and air ducts above exposed product.
 b) Beaded condensate was observed above exposed product in Salami Cooling Rooms # 1,2,3,4, and Proscuitto Cooling Room # 10. The floors under the beaded condensate were wet indicating the condensate had dripped onto the product.
 c) In the cooling room, strings from salami stockinet were resting on the floor presenting the potential for product adulteration. The establishment was slow in implementing immediate corrective actions due to implication of several salami rooms in over product condensation [Regulatory reference: 9CFR 416.13 (a)-(c)]
- 25 In the packaging material room an unlabeled tub containing ingredients used in formulation in the salami product was observed. [Regulatory reference: 9CFR 318.1(c)]
- 38/51/56a) A space approximately one foot wide, between the wall of the receiving dock and a tarpaulin covering the door of the receiving dock was littered with debris and miscellaneous objects dampened with stagnant water.
 b) A green tarpaulin covering the exterior of the chemical room wall was frayed, torn and appeared grossly dirty.
 c) An alley between the chemical room wall and another adjacent structure had collected water from an undetermined source that was stagnant and emitted a repugnant smell. The alley was littered with miscellaneous trash and debris.
 d) A discarded grinding chopper was used as a waste bin. Soda cans, cardboard boxes, and other objects were found floating in stagnant water in the hopper. This posed insanitary conditions and caused potential for rodent harborage. [Regulatory reference: 9CFR 416.2 (a)] [[EC Directive 64/433]
- 39/51/56a) Holes measuring one inch in diameter were observed in the wall of Salami Cooler Room.
 b) Rust was observed at the base of a holding rack used to hang salami product.
 c) A few plastic trays used in product preparation were cracked preventing thorough cleaning and sanitation.
 d) The freezer door gasket was frayed and torn at numerous places.
 e) Water seepage in the left front corner of the packaging material storeroom was eroding the wall and causing moisture accumulation in the corner. [Regulatory reference: 9CFR 416.2 (b)(2&3)] [[EC Directive 64/433]
- 44/51/56A cobweb with trapped insects was observed in a lavatory located near package storing room. [Regulatory reference: 9CFR 416.2 (h)] [[EC Directive 64/433]
- 46/51/56a) A container of corrosive chemical was stored in a utility cabinet in the processing room.
 b) A loose roll of stockinet used as outer covering on the salami product was improperly stored on a shelf creating a potential for cross contamination.
 c) An open paint container was observed stored in the chemical room and was creating insanitary conditions and a potential for cross contamination. [Regulatory reference: 9CFR 416.4(b)] [[EC Directive 64/433]
- 59 The veterinarians from ASL, MOH and Toscana region who led the audit delisted the establishment from the list of certified establishments eligible to export to US.

61. NAME OF AUDITOR
 Alam R. Khan DVM

62. AUDITOR SIGNATURE AND DATE

W. Mangool H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION B E B Prosciutti SRL Via Giacomo Pirona 15 33038 San Daniele del Friuli (UD) Italy	2. AUDIT DATE 04/03/2008	3. ESTABLISHMENT NO. 683L	4. NAME OF COUNTRY Italy
	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	
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.		38. Establishment Grounds and Pest Control	X
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.		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	X
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.		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	X
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: 04/03/2008 Est #: 683L (B E B Prosciutti SRL [P]) (San Daniele del Friuli, Italy)

38/51/56 a) Miscellaneous discarded equipments and wooden pallets were stored improperly posing possible harborage of rodents in and around the equipment.

b) Several containers of chemicals were stored insecurely on the outside premises of the establishment.

The official veterinarian gave assurance that the findings will be removed immediately. [Regulatory reference: 9CFR 416.2 (a)][EC Directive 64/433]

39/51 In a ham drying room the following were observed:

a) Water was running freely on the floor in the room due to a faulty valve located in the temperature control unit. product in the room was not affected.

b) Readily flaking paint was present on a motor mounted on the unit, no product stored near the motor.

c) Two valves located in the plumbing of the unit were leaking; no exposed product was stored in the vicinity of leaky valves.

The ASL official veterinarian ordered immediate correction for items a and c, and gave assurance that the finding identified in item b would be corrected as soon as possible. [Regulatory reference: 9CFR 416.2 (b)(2) & (c)(3)][EC Directive 64/433]

46/51/56 Hog hair was observed covering 1/3 of the ham surface on several hams in the shipping room. Visible extraneous material from a source other than charred brand marks was also observed on these hams. The ASL official veterinarian took immediate control action. [Regulatory reference: 9 CFR 416.4 (d) & 310.18] [EC Directive 64/433]

61. NAME OF AUDITOR

Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

for Mangoor H. Chaudry 8/4/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Italcami Societa, Cooperativa, Agricola. Via per Guastalla, 21/A 41012 Migliarina di Carpi (MO)	2. AUDIT DATE 04/21/08	3. ESTABLISHMENT NO. 791MS L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alan 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)	Audit Results	Part D - Continued Economic Sampling	Audit Results
Basic Requirements			
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	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	X
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.		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	
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	X
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

Date: 04/21/08 Est #: 791MS L (Italcarni Soc. Coop. A.R.L. {}) (Capri, Italy)

- 10 The following observations were made during the pre-operational sanitation verification:
- a) Mixtures of mud, hair, grease and other debris was observed on the railings in the scalding.
 - b) Hair, debris and grease build-up was observed on non food contact surfaces of two de-hairer machine in the kill floor.
 - c) Several dead insect/flyes were observed adhered to a wall near a sterilizer in the sticking area.
 - d) Unidentifiable dead and live insects, mud, and hair were found on the stunning conveyor belt. Hair, blood, fat and grease were also observed on a second conveyor belt identified as the shaving belt.
 - e) A sterilizer used to sanitize knives and steels had a mixture of hair and fat residues from the previous day's operation.
 - f) Hair, fat, meat residue and dirt were found in many sinks in the kill floor and evisceration room, one sink in the boning room had meat particle and dirt in it.
 - g) Rust was observed along the entire length of a ready to use knife steel.
 - h) In the processing room, a ready to use apron washing machine was observed with gross fat and meat particles on the brush rollers and panels from the previous day's operation.
 - i) A door separating the scalding area and the carcass flaming room had un-cleaned door panels. The establishment delayed the operation, and corrected all the deficiencies identified in item a-f.
- [Regulatory reference: 9 CFR 416.13 (a-c)]
- The following observations were made during operational sanitation verification.
- a) Grease smudges were observed on the carcasses entering the process room, on the hams stored in Chiller 10A and on the conveyor belt in the processing room. The line was stopped to bring the problem in control. The hams in the chiller 10A were retained for rework. [Regulatory reference: 9 CFR 416.3 (c)]
 - b) Excessive hair was observed around the front feet of the carcass on the processing table. The forelimbs were removed after the product had passed the processing table. No plan was proposed to correct the findings either by the management or by the inspection.
- [Regulatory reference: 9 CFR 416.3 (c)]

38/51/56 Water had collected in pits on the grounds next to the inedible shipping area. The grounds around the gate were poorly maintained and had accumulations of litter present. [Regulatory reference: 9CFR 416.2 (a)] [[EC Directive 64/433]

46/51/56 Water was dripping from a rusty valve in the area where employees were removing pork heads from the carcasses. The establishment corrected the problem immediately. [Regulatory reference: 9CFR 416.4(b)] [[EC Directive 64/433]

51 The inspector's pre-operational document did not identify any problem listed in item 10.

The Italian officials leading the audit issued the establishment NOID due to SSOP and SPS findings observed during the audit

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

W Mangoor H. Chaudhry 8/4/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Stagionature Fumagali s.r.l Via Cascinapiano, 60 43013 Langhirano (PR)	2. AUDIT DATE 04/16/2008	3. ESTABLISHMENT NO. 1036L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alan 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	[REDACTED]	33. Scheduled Sample	
8. Records documenting implementation.	[REDACTED]	34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	[REDACTED]	35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	[REDACTED]	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	[REDACTED]	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	[REDACTED]	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	[REDACTED]	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.	[REDACTED]	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	[REDACTED]	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	[REDACTED]	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	[REDACTED]	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	[REDACTED]	46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	[REDACTED]	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	[REDACTED]	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	[REDACTED]	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	[REDACTED]	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	[REDACTED]	51. Enforcement	X
24. Labeling - Net Weights	[REDACTED]	52. Humane Handling	O
25. General Labeling	[REDACTED]	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	[REDACTED]	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	X
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: 04/16/2008 Est #: I036L (Salumificio Casett Di Piazza W.EC.SNC [P]) (Langhirano, Italy)

46/51/56 Dead spiders and insects were found in one corner of a dry cured ham aging room. Cobwebs were also found at more than one place in the same room. Immediate corrective actions were initiated by the regional supervisor present at the audit. The establishment corrected the deficiency before the audit was over.
[Regulatory reference: CFR 416.4(b)] [EC Directive 64/433]

61. NAME OF AUDITOR

Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

by Manjoor H. Chaudry 8/4/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Selva Alimentari S.p.A Via Aonedis, SSNN 33038 San Daniele Del Friuli (UD) Udine Italy	2. AUDIT DATE 4/2/08	3. ESTABLISHMENT NO. 2002L	4. NAME OF COUNTRY Italy
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	
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.		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.		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	X
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.		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	X
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: 4/2/08 Est #: 2002L (Selva Alimentari SPA [P]) (San Daniele Del Friuli, Italy)

39/51/56 The pits measuring 2" x 2" x 2" in the floor of the ham fat smearing room had collected dirt and grease in them producing insanitary condition. The official veterinarian gave assurance that these pits will be cemented very soon. [Regulatory reference: 9CFR 416.2 (a)] [[EC Directive 64/433]

46/51/56 a) Excessive hair was observed on a dried/cured ham in the shipping room.

b) A ready to be salted fresh ham that had passed the controls at the receiving step had a tuft of hair approximately 2" long. The products implicated in both findings were retained by the official veterinarian [Regulatory reference: 9 CFR 416.4 (d) & 310.18; C/D] [EC Directive 64/433 EEC Annex 1 Chapter V]

61. NAME OF AUDITOR

Alam R. Khan DVM

62. AUDITOR SIGNATURE AND DATE

Dr. Mangool H. Chaudry 8/4/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Grandi Salumifici Italiani Via Pizach 11 39038 San Candido, (BZ)	2. AUDIT DATE 04/07/08	3. ESTABLISHMENT NO. 675L	4. NAME OF COUNTRY Italy
	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	
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.		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.		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	X
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.		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	X
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: 04/07/08 Est #: 675L (Grandi Salumifici Italiani [P]) (San Candido, Italy)

39/51/56 In some production rooms and the packaging room openings were not sufficiently sealed around plumbing and electrical ducts entering ceilings and walls. This could pose potentials for entry of pests into the food production area. The inspection officials took immediate control action. [Regulatory reference: 9CFR 416.2 (b)] [EC Directive 64/433]

46/51/56 Ready to use molds for ham product had meat and fat residues present on the inner surface from previous day's production posing insanitary conditions and potentials for the cross contamination. [Regulatory reference: 9CFR 416.4 (a)] [EC Directive 64/433]

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

Al Manjoor H. Chaudry 8/4/08



Ministero della Salute

0029527-P-15/10/2008

DGSRN 1.2.a.c.1



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*Ministero del Lavoro, della Salute
e delle Politiche Sociali*

**DIPARTIMENTO PER LA SANITA' PUBBLICA VETERINARIA, LA NUTRIZIONE E LA
SICUREZZA DEGLI ALIMENTI**
DIREZIONE GENERALE DELLA SICUREZZA DEGLI ALIMENTI E DELLA NUTRIZIONE
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Stati Uniti d'America
Roma
Fax n° 06-47887008

Subject: Draft Final Report (FSIS Audit Mar. - Apr. 2008)

Dear Donald Smart,
thanks for your letter of 08-23-08.

We received the Draft related to the last FSIS mission to Italy. We just would like to specify that in the report the approval numbers of some establishments are not correct. F.lli Martelli is 643 M and Italcarni is 791 M. All the non conformity indicated in the draft are treated by ASL moreover the NOID was closed by MOH in respect of the recommended time.

Do not hesitate to contact us for any further information.

Best regards,

Silvio Bonello
General Director