



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
Piazza Marconi, 25-00144
Rome, Italy

AUG 02 2007

Dear Dr. Borrello:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Italy's meat inspection system February 22 to March 19, 2007. Comments from Italy have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

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

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

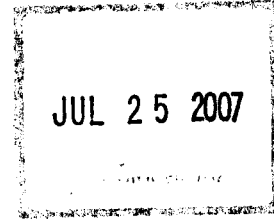
Enclosure

cc list:

Geoffrey Wiggin, Minister-Counselor, US Embassy, Rome
Andrea Canepari, First Commercial Secretary, Embassy of Italy
Canice Nolan, First Secretary, EU Mission to the US, Washington
Debra Henke, Minister-Counselor, US Mission to the EU, Brussels
Bernard Van Goethem, Acting Director, Directorate E, European Commission, Brussels
Alfred Almanza, Administrator, FSIS
Robert Macke, ADA, OSTA, FAS
David Young, FAS Area Officer
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Clark Danford, Director, IEPS, OIA
Mary Stanley, Director, IID, OIA
Barbara McNiff, Director, FSIS Codex
Marsha Singer, State Department
Nancy Goodwin, IES, OIA
Italy Country File

FSIS:OIA:IAS:D SMART:402.344.5100:8/03/07:Italy Audit Final Letter August 07

FINAL



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

February 23 through March 19, 2007

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

TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
 - 6.1 Legislation
 - 6.2 Government Oversight
 - 6.3 Headquarters Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
 - 9.1 SSOPs
 - 9.2 SPS
 - 9.3 EC Directive 64/433
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
 - 11.1 Humane Handling and Slaughter
 - 11.2 HACCP Implementation
 - 11.3 Testing for Generic *Escherichia coli*
 - 11.4 Testing for *Listeria monocytogenes*
 - 11.5 EC Directive 64/433
12. RESIDUE CONTROLS
 - 12.1 FSIS Requirements
 - 12.2 EC Directive 96/22
 - 12.3 EC Directive 96/23
13. ENFORCEMENT CONTROLS
 - 13.1 Daily Inspection
 - 13.2 Testing for *Salmonella*
 - 13.3 Species Verification
 - 13.4 Monthly Reviews
 - 13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (The Ministry of Health)
<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 February 23 through March 19, 2007.

An opening meeting was held on February 23 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 (MOH) and/or representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual 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, one regional inspection offices, two local inspection offices, one government residue and microbiology laboratory performing analytical testing on United States-eligible product, two pork slaughter establishments, and six pork processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Rome
	Regional	1	Lombardia
	Local	2	Magenta,Udine
Laboratories		1	Brescia IZS
Meat Slaughter Establishments		2	
Processing Establishments		6	

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 visits to one regional office and two local government offices. The third involved on-site visits to eight establishments: two slaughter establishments, and six processing establishments. The fourth part involved a visit to one government residue and microbiology laboratory, the Istituto Zooprofilattico Sperimentale (IZS) in Brescia. The laboratory was conducting analyses of field samples for residues and microbiology for the establishments certified to export product 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 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 the production of meat products are safe, unadulterated and properly labeled.

At 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 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 that have been recognized as equivalent are:

1. Government laboratories use ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella*.
2. Italy can use five 75-gram samples to test Ready-To-Eat (RTE) 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 FSIS audits of Italy’s meat inspection system were conducted in March 2005 and November 2005.

During the FSIS audit conducted in March/May 2005, the following deficiencies were identified:

- In seven establishments, the MOH was not enforcing all of FSIS’ inspection requirements.
- In six of 13 establishments, deficiencies in sanitary operations were observed.
- In five of 13 establishments, implementation of SSOP with sanitation procedures preventing product contamination was deficient.
- Three establishments were issued a Notice of Intention to Delist (NOID) by the MOH because of SSOP and SPS deficiencies.
- In two of 13 establishments, corrective action to prevent direct product contamination was not effective.
- In two of 13 establishments, deficiencies regarding equipment and utensils were observed.
- Although the MOH had audited the three establishments that received the NOIDs, there was no follow-up by the MOH to verify that corrective actions had been taken in two of the three establishments.
- In three laboratories, there was improper implementation or improper adaptation of ISO 6579:2002 when testing U.S. samples of raw products and ready-to-eat products for *Salmonella*.

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

- One establishment was issued an NOID by the MOH because of SSOP and Sanitation Performance Standards deficiencies.
- In six establishments, the MOH was not enforcing all of FSIS' inspection requirements.
- In five of the 13 establishments, implementation of the SSOP with sanitation procedures preventing product contamination was deficient.
- In two of 13 establishments, deficiencies in sanitary operations were observed.
- In two of 13 establishments, deficiencies in establishment grounds and pest control were observed.

During this audit, it was found that the deficiencies identified in the last two audits had been corrected.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

MOH has the organizational structure and staffing to ensure uniform implementation of U.S. requirements. The Office of Veterinary Public Health, Nutrition and Food Safety (OVPHNFS) was elevated to the Department level.

6.2.1 CCA Control Systems

Italy's organizational structure has not changed since the FSIS audit conducted in November/December 2005.

The Office of Veterinary Public Health, Nutrition and Food Safety (OVPHNFS) Department oversees nine sub-offices including the Office for Food Safety (Office III). The head of the Office of Veterinary Public Health, Nutrition and Food Safety reports directly to the MOH.

The CCA has control over regional and local office activities and has the authority for certifying and decertifying establishments for export to the United States. The CCA is responsible for carrying out inspections of individual establishments and for approving and withdrawing the eligibility of individual establishments.

6.2.2 Ultimate Control and Supervision

The CCA has ultimate control over all establishments certified for export to the United States. However, in one of the Regions (Lombardia) it was noted during the audit that there was a significant lack of control and supervision exercised by inspection officials, and a failure to adequately enforce inspection requirements. This weakness in oversight in the Lombardia Region had not been previously identified by the CCA.

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

Although, MOH has the authority and the responsibility to enforce U.S. and E.C. requirements, all of U.S. requirements were not enforced in seven establishments. Significant issues were noted in the Lombardia Region, leading to the delisting of one establishment with another establishment receiving a Notice of Intent to Delist.

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, one regional, two local, and all in-plant inspection offices located in the eight establishments audited. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- 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.

6.3.1. Audits of Regional and Local Inspection Sites

One regional office was audited: Lombardia

The following concerns arose as a result of these audits.

- Audits conducted by the Lombardia Regional office did not adequately identify/correct failures to enforce inspection requirements.

Two local offices were audited: Udine and Magenta

No concerns arose from the audit of local offices

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of eight establishments. Two were pork slaughter establishments, and six were pork processing establishments. One establishment was delisted and one received a NOID from the MOH because of SSOP and SPS implementation deficiencies. The establishment which received the NOID may retain its certification for export to the United States provided that the management corrects all deficiencies noted during the audit within 30 days of the date the establishment was audited, or it is to be delisted by MOH. 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.

The following residue and microbiology laboratory was audited:

The Istituto Zooprofilattico Sperimentale laboratory in Brescia was conducting analyses of field samples for residues and microbiology.

No deficiencies were observed.

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. The SSOP in the eight establishments that were audited was found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In two of eight establishments, implementation of the SSOP was ineffective in preventing product contamination.
- In five of eight establishments, preventive measures were not included as part of SSOP corrective actions.

9.2 SANITATION PERFORMANCE STANDARD

- In three of eight establishments, deficiencies in sanitary operations were observed.
- In two of eight establishments, deficiencies in establishment grounds and pest control were observed.
- In one of eight establishments, deficiencies in maintenance of equipment and utensils were noted.
- In six of eight establishments, deficiencies in construction and maintenance were noted.

9.3 EC Directive 64/433

In six of eight establishments, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies were identified and are noted in the attached individual establishment reports.

In three of eight establishments, deficiencies in sanitary operations were observed.

- In one of eight establishments, deficiencies in maintenance of equipment and utensils were noted.
- In two of eight establishments, deficiencies in maintenance of establishment grounds and pest control were noted.
- In six of eight establishments, deficiencies in construction and maintenance were noted.

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.

11.1 Humane Handling and Humane Slaughter

No deficiencies were observed.

11.2 HACCP Implementation

- In four of eight establishments, the verification and/or validation of the HACCP plan was deficient.
- In three of eight establishments, the preventive measures for corrective actions were not recorded when deviations from critical limits occurred.

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

In all establishments, the provisions of EC Directive 64/433 were effectively implemented.

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 *Instituto Zooprofilattico Sperimentale* laboratory located in Brescia was conducting analyses of field samples for the presence of residues. No deficiencies were observed.

Italy's National Residue Control Program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In the *Instituto Zooprofilattico Sperimentale*, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the *Instituto Zooprofilattico Sperimentale*, the provisions of EC Directive 96/23 were effectively implemented.

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, in all eight establishments audited.

13.2 Testing for *Salmonella* Species

The two slaughter establishments which were 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

Periodic supervisory reviews of certified establishments were being performed and documented.

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 establishments; and prevention of commingling of product intended for export to the U.S. 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.

The MOH was not enforcing some of FSIS's inspection requirements.

14. CLOSING MEETING

A closing meeting was held on March 19, 2007 in Rome with the CCA. At this meeting, the primary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Alam Khan
Senior Program Auditor

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

15. ATTACHMENT

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Giuseppe Citterio Salumificio S.p.A. Corso Europe, 206 Rho (MI) 20017	2. AUDIT DATE March 7, 2007	3. ESTABLISHMENT NO. 311,	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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	
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	
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	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

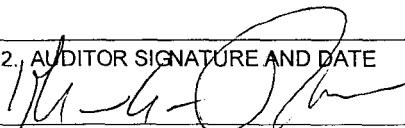
Date: 03/07/2007 Est #: 31L (Giuseppe Citterio Salumificio S.p.A. [P]) (Rho (MI), Italy)

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

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Principe Di San Daniele S.p.A. Via Venezia, 222/224 San Daniele Friuli (UD) 33038	2. AUDIT DATE March 13, /2007	3. ESTABLISHMENT NO. 2051,	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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: Est #: 205L (Principe Di San Daniele S.p.A. [P]) (San Daniele Friuli (UD), Italy)

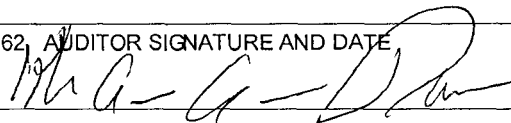
15/51 The establishment's HACCP plan did not include a flow diagram or documentation of a hazard analysis for reworked product. The local government official leading the audit gave assurance that she would follow-up on this correction. [Regulatory references: 9CFR 417.2(a) (1) (2) and 417.8]

45/51/56 In the raw-product receiving area, the rubberized sleeves on equipment for handling incoming hams were partially deteriorated from the salt used on the hams. The establishment management would correct the deficiency as soon as possible. [9CFR 416.3(a), 416.17, and EC Directive 64/433, Annex 1, Ch. II (2)(n)]

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION MEC-Carne S.P.A. Via PM Virgilio, 22 Marcaria (Montova) 46010	2. AUDIT DATE Feb. 28, 2007	3. ESTABLISHMENT NO. 304MS	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
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.	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	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		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	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: 02/228/07 Est #: 304MS (MEC-Carne S.P.A. [S]) (MARCARIA (MONTOVA), Italy)

- 15/51 Reworked product had not been included in the flow chart or considered in the hazard analysis. [Regulatory references: 9CFR 417.2 and 417.8]
- 19/51 The frequency for verification of thermometer calibration was set at once per year, but no supporting documentation for the selection of this frequency was presented. [Regulatory references: 9CFR 417.5(2) and 417.8]
- 22/51 In documenting corrective actions for a deviation from critical limits, the establishment did not specify measures to prevent recurrence.
The local government official leading the audit gave assurance that he would follow up on the corrections for the deficiencies listed above. [9CFR 417.5(a)(3) and 417.8]
- 38/51/56 Mold, slime and vegetation had been allowed to grow on the grounds enclosed between the slaughter room on one side and processing rooms on the other two sides. Old, rusty, discarded equipment, miscellaneous metallic junk, and a steel bucket filled with dirty rain water were observed stored on the ground in this area. Also, stagnant water, slime, and mold were observed on the grounds around the inedible storage room. These conditions posed potential harborage areas for vermin. The establishment would correct the deficiency immediately.
[9CFR 416.2(a), 416.17, and EC Directive 64/433, Annex 1, Chapter 111, 3]
- 39/51/56 The caulking used to bind fiberboard panels to walls and floors in the processing room was frayed, and loose, creating wide gaps between the board and the wall. The caulking was also missing in several places, creating potential for water seepage in the spaces behind the board. The establishment had documented plans that the fiberboard panels would soon be replaced with permanent material. [9CFR 416.2(b)(2), 416.17, and EC Directive 64/433, Annex 1, Chapter 11(e)]

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



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. Berreta, 5 Medolago (BG) 24030	2. AUDIT DATE March 6, 2007	3. ESTABLISHMENT NO. 368T	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	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	
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. NOID	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 03/06/2007 Est #: 368L (Wuber S.p.A. [P/CS]) (Medolago (BG), Italy)

- 10 **a)** Unidentified foreign material was observed on the shanks of hams in the receiving cooler.
[Regulatory reference: 9CFR 416.13(c)]
- b)** A heavy grease buildup was observed around rotator shafts of the tumbling machines, in close proximity to exposed product. [9CFR 416.13(c)]
- c)** Heavy buildups of product residues were found on the metal moulds used the in manufacturing of pressed hams. [9CFR 16.13(c)]
- d)** Procedures for condensation monitoring were not being performed as specified in the written SSOP. [9CFR 416.13 (b)]
- Immediate corrective action was requested by the local government official leading the audit and the establishment complied.
- 13/51 Preventive measures were not included as part of the documentation of corrective actions taken in response to SSOP deficiencies. The local government official leading the audit gave assurance that he would follow up on the correction. [9CFR 416.15(b) and 416.17]
- 39/51/56 **a)** The rubber gaskets in the doors of the cooking ovens were deteriorated and in need of repair or replacement. [9CFR 416.3(a), 416.3(a), 416.17, and EC Directive 64/433, Annex 1, Ch. II(2)(n)]
- b)** Rust was observed on rails used for supporting racks of product. [9CFR 416.3(a), 416.17, and EC Directive 64/433, Annex 1, Ch. II(2)]
- c)** Several tumbler vessels had rough welds. [9CFR 416.3(a), 416.17, and EC Directive 64/433 Annex 1, Ch. II(2)]
- d)** A cover panel of the de-moulding assembly was covered with a thin layer dirt and grease. (Product passing through the assembly was covered in plastic. [9CFR 416.3(a), 416.4(b), and EC Directive 64/433 Annex 1, Ch. II(2)(n)]
- With the exception for the deficiency listed in item d which had been corrected immediately, the establishment management would issue work orders for deficiencies described in items a-c as soon as possible.
- 58 The officials from MOH and ASL leading the audit issued a Notice of Intent to Delist to the establishment due to SSOP and SPS issues identified above.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rovagnati S.p.A. Via E. Fermi, 19 Biassono (MILANO) 20046	2. AUDIT DATE 03/05/2007	3. ESTABLISHMENT NO. 508I.	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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.	X	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.	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	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		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

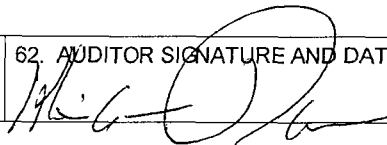
Date: 03/05/07 Est #: 508L (Rovagnati S.p.A. [PJ]) (Biassono (MILANO), Italy)

- 13/51 a) The establishment was not documenting the monitoring of all the equipments/food contact surfaces which they had implemented and identified in their pre-operative SSOPs. [Regulatory references: 9CFR 416.14(a)]
b) The establishment was not documenting the monitoring of employees hand washing practices which they had implemented in the cooked ham area as an additional measure to control *Listeria monocytogenes* through their operational Sanitation SOPs. [9CFR 416.14(a)]
- 15/51 Rework products were not included in the flow chart and were not considered in the hazard analysis. [9CFR 417.2]
- 19/51 The frequency for verification of thermometer calibration was set once a year, no supporting documents for the selection of the frequency was presented. The Local government officials gave assurances that they would follow up on the correction of deficiencies identified above. [9CFR 417.5(2)]
- 39/51/56 Construction debris including nails, wood chips pieces of plastic sheet and dirt was observed littering the floor of the finished packaged product cooler where a wall opposite to the entrance was being rebuilt. The wall was only partially covered with the heavy plastic sheet. An employee utility locker was also stored in the cooler had a layer of dirt on its roof. The local government official leading the audit requested the immediate compliance, and the establishment management immediately initiated the cleaning. The management gave assurance that the renovation projected will be completed soon. [9CFR 416.2(b)(2)] Directive 64/433, Annex 1, Chapter 111, 3
- 46/51/56a) A utility locker was noted stored on the floor of the cooking area opposite the ovens. This locker was used to store articles like work boots, sleepers, used work jackets, bottles of glass cleaner, a bottle of drinking water, tools, rubbing alcohol, etc. The establishment immediately cleaned the locker and restored its use only to keep hand tools required for ovens maintenance. [9CFR 416.5(a)] Directive 64/433, Annex 1, Chapter 111, 3
b) In the brine injection room a dirty clothed apron was observed hanging with the clean plastic aprons. The establishment management discarded the apron. [9CFR 416.5(b)] Directive 64/433, Annex 1, Chapter 111, 3

61. NAME OF AUDITOR

Alam Khan DVM

62. AUDITOR SIGNATURE AND DATE



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 Doslo (Mantova) 46030	2. AUDIT DATE March 1, 2007	3. ESTABLISHMENT NO. 643MS	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
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.	X	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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. Delistment	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 03/01/2007 Est #: 643MSL (Martelli F.LLi s.p.A [S/P]) (Doslo (Mantova), Italy)

- 10 The following observations were made during pre-operational sanitation verification:
- a) One of the two brisket saws on the evisceration line, had a thick layer of fat and meat deposits between the inner face of the brisket case and the wheel for the blade.
 - b) Numerous white plastic aprons, ready to be used, were stained with blood and had fat and meat deposits on them. A number of aprons that were in use had blood stains and excessive buildups of fat and meat.
 - c) The shaft of a shank cutter had a deposit of fat from the previous day's operations.
 - d) Fat deposits were observed under a cutting board and on the frame of the rework table.
 - e) In the processing room, one end of the long S-shaped stainless rod used to pick up dropped meat from the floor had a fat deposit from the previous day's operations.
 - f) Meat and fat deposits were observed on a wall, on hooks, and on a roller brush in the ham washing cabinet in the processing room.
 - g) Several viscera pans were found with extraneous material and product residues from the previous day's operations.
- Immediate corrective actions were taken by the establishment. All the items identified in a-g were presented again for pre-op sanitation verification. [Regulatory reference: 9CFR 416.13(c)]
- 13/51 The establishment was not documenting preventive measures as part of corrective actions in their daily records for pre-operational and operational sanitation records. The local government official requested immediate compliance from the establishment. [9CFR 416.16(a) and 416.17]
- 19/51 The critical limit in the coolers for CCP 2B had been set at 7°C; no supporting documentation for the selection of the CL was presented for review. The local government official leading the audit requested immediate compliance from the establishment. [9CFR 417.4(a) and 417.8]
- 22 Two carcasses which had passed the final inspection station had unidentified extraneous material around their shank and neck regions. These carcasses were contacting each other and other carcasses. Immediate corrective actions were taken by the establishment. [9CFR 416(c)]
- 22/51 The establishment did not address, in its HACCP plan, preventive measures as part of corrective actions when a deviation from a critical limit is identified. The local official veterinarian requested immediate compliance from the establishment. [9CFR 417.3 (a) and 417.8]
- 39/51/56 The wall/floor junctions in the washed equipment room had numerous broken or missing tiles. The establishment will replace broken or missing tile immediately. [9CFR 416.3(a), 416.17, and] EC Directive 64/433 Annex 1, Ch. III(4)]
- 45 Racks for inedible materials were observed with numerous pieces of fat and meat left from the previous day's operations. Immediate corrective actions were initiated and completed while audit was still in progress. [9CFR 416.3(c)]
- 46/51/56 **A)** A potable waterline above the inspection station had flaking peeling paint. **B)** A large white plastic garbage bag soiled with spots of dirt mixed with water was used to cover an electric control box for stunning electrodes. **C)** The conveyor belt for carrying pigs after bleeding to the hoisting chain had deposits of bloody material. **D)** An open drain line under the conveyor belt had fat and blood stains from the previous day's operations. **E)** The heavy plastic curtains covering scalding tanks were soiled with deposits of mud, hair and unidentified material. **F)** Grease buildup was observed on one of the pulleys above the conveyor belt in the processing room. Immediate corrective actions were initiated and completed while audit was still in progress. [9CFR 416.4(a)-(d), 416.17, and EC Directive 64/433 Annex 1, Ch. III(4)]
- 58 The officials from MOH and ASL (Local Office) leading the audit Delisted the establishment from exporting to the US. Note: This establishment had received a Notice of Intent to Delist during the previous FSIS audit, conducted in November 2005.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION A e B Prosciutti S.p.A. San Daniele del; Friuli -Loc-Aonedis, 11 (UD) Friuli (UD) 11	2. AUDIT DATE March 12, 2007	3. ESTABLISHMENT NO. 7201.	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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	
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	
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	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 03/12/07 Est #: 720L (A e B Prosciutti S.p.A. [P]) (Friuli (UD), Italy)

13/51 Preventive measures were not included as part of the daily documentation of corrective actions taken in response to sanitation deficiencies. [Regulatory references: 9CFR 416.15(b) and 416.17]

15/51 **A)** The establishment's HACCP plan did not include a flow diagram or documentation of a hazard analysis for reworked product. [9CFR 417.2(a)(1)(2) and 417.8]

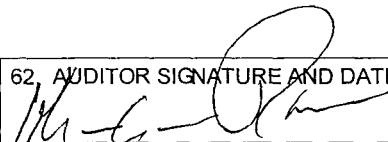
B) Several processing steps included in the product flow diagram had not been considered in the hazard analysis. [9CFR 417.2(a) (2) and 417.8]

The Local government officials gave assurances that they would follow up on the correction of these deficiencies.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Parmacotto S.p.A. Via Conforti 21 Parma 43100	2. AUDIT DATE March 8, 2007	3. ESTABLISHMENT NO. 7441	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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.	X	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.	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	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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: 03/08/2007 Est #: 744L (Parmacotto S.p.A. [P]) (Parma, Italy)

13/51 **A)** In the written SSOP plan for operational sanitation, knife cleaning was to be monitored once daily, however, no records related to the monitoring of knife cleaning was available. **B)** The establishment was not documenting preventive measures for corrective actions in its daily records for pre-operational and operational sanitation. [Regulatory references: 9CFR 416.16 (a) and 416.17]

15/51 The establishment's HACCP plan did not include a flow diagram, or documentation of a hazard analysis for reworked product. [9CFR 417.2(a)(1)(2) and 417.8]

19/51 The establishment did not present supporting documentation for the selection of frequencies for calibration of thermometers and the verification of the thermometer calibration. [9CFR 417.4 (a) (2) and 417.8]

22/51 The establishment did not address, in the HACCP plan, preventive measure as part of corrective actions when a deviation from a critical limit was identified. [9CFR 417.3(a) and 417.8]
The Local government officials gave assurances that they would follow up on the correction of deficiencies identified above.

38/51/56 **A)** The premises around one shipping and receiving dock was poorly maintained. Long plastic strips protecting the opening were soiled, torn and missing in one place. **B)** Mold and vegetation had been allowed to grow on the grounds along one side of a wall near the loading area; two old, rusty racks were also observed stored in this area. [9CFR 416.2(a) and EC Directive 64/433 Annex 1, Ch. III(4)]

39/51/56 A rubber gasket and its metallic mounting rim on a shipping door on the loading/unloading dock was torn and twisted, leaving a gap on closing, thus creating a potential entry for vermin into the food-handling areas. [9CFR 416.2(b) and EC Directive 64/433 Annex 1, Ch. III(4)]
The establishment will immediately issue work order to correct deficiencies identified above.

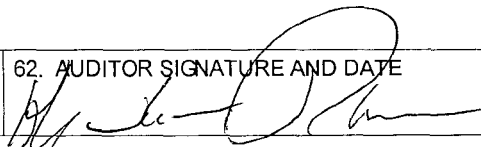
45/51/56 **A)** The cover panel of an electrical control box for a tumbler had a buildup of an unidentified gluey substance and fluid leaking from an overhead condenser. **B)** Multiple tumblers had rough welds, creating the potential for inadequate cleaning and sanitization of the equipment. [9CFR 416.3(a) and EC Directive 64/433 Annex 1, Ch. II(2)(n)]
This deficiency was corrected by the establishment before the audit was over.

46/51/56 In the ingredients room, rails embedded in the floor of the room were corroded and one corner of the room was littered with dirt and debris. [9CFR 416.4(b) and EC Directive 64/433 Annex 1, Ch. II & III]
The establishment has notified maintenance for immediate corrective actions.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE





Ministero della Salute

DIPARTIMENTO PER LA SANITA' PUBBLICA VETERINARIA, LA NUTRIZIONE E
LA SICUREZZA DEGLI ALIMENTI
DIREZIONE GENERALE DELLA SICUREZZA DEGLI ALIMENTI E DELLA NUTRIZIONE
Ufficio IX

25 LUG. 2007

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DGSAN/IX/ 9423 | P

Subject: Draft Final Report (FSIS Audit Feb. - Mar. 2007)

Dear Donald Smart,
thanks for your letter of 05-30-07.
We received the Draft and here we attach our comments (Annex).
Do not hesitate to contact us for further information.
Best regards,

Silvio Borrello
General Director

Annex: 1 page

Comments to FSIS Draft Final Report

Noncompliance n° 15 in establishments 304 M, 508L, 744L, 205L and 720L: the arrow of the reworked product in the flow chart is missing.

We specify that rework of the product is not expected in some of those establishments; however, if rework of the product means the toilet of contaminated product, we will work to extend this information also to other establishments.

Noncompliance n° 19 in establishments 304 M, 508L and 744L: the documentation supporting selection of frequencies decided by companies for verification of thermometer calibration lacks of scientific evidence.

Producers of instruments specify that the frequencies of instruments calibration can't be set in a general way, but depend on the use and experience: all the establishments calibrate the secondary instruments on the basis of their experience; for what concerns the electronic thermometers certified as reference, constructors recommend to verify them every 10 or 15 years: this gap time is very high considering the frequencies adopted by the establishments (usually 1 or 3 years).

Regulation of the species verification was updated during the last U.S.A. - Italy Bilateral Meeting of June 6 and 7, 2006:

- species verification is not mandatory for anatomically recognizable products;
- species verification is mandatory for anatomically not recognizable products: it is continuous if the establishments work different species meat products; it's not continuous if the establishments produce only swine meat products and the frequency is decided by the Local Veterinary Services.