United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAY 15 2006

Dr. Silvio Borrello
General Director
Department of Food and Nutrition
and Public Veterinary Health
Ministry of Health
Piazza Marconi, 20-00144
Rome, Italy

Dear Dr. Borrello:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in Italy from November 4 through December 15, 2005. Italy did not provide any comments in response to the draft final report. Enclosed is a copy of the final report.

If you have any questions about this audit or need additional information, please contact me at 202-720-3781, facsimile 202-690-4040, or e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White JD

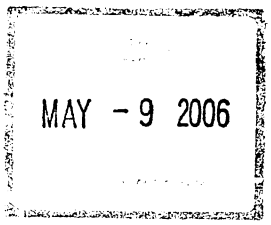
Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Geoffrey Wiggin, Counselor, US Embassy, Rome
Maria Trinchieri, Commercial Attaché, Embassy of Italy, Washington
Canice Nolan, EU Mission to the US, Washington
Norval Francis, Minister/Counselor, US Mission to the EU, Brussels
Barbara Masters, Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA
William James, Deputy Assistant Administrator, OIA
Scott Bleggi, FAS Area Officer
Robert Macke, ITP, FAS
Sally White, Director, IES
Donald Smart, Director, Review Staff, OPEER
Clark Danford, Director, IEPS
Barbara McNiff, Director, FSIS Codex
Mary Stanley, Director, IID
Linda Swacina, Director, FSIA
Amy Winton, State Department
Nancy Goodwin, IES, OIA
Italy Country File—Audit Nov05

FINAL



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

November 4 through December 15, 2005

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

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)
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points Systems
Lm	*Listeria monocytogenes*
MOH	Ministry of Health
NOID	Notice of Intent to Delist
Salmonella	*Salmonella* 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 November 4 through December 15, 2005.

An opening meeting was held on November 4 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 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, five regional inspection offices, five local inspection offices, one government residue and microbiology laboratory performing analytical testing on United States-eligible product, two pork slaughter establishments, and 11 pork processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Rome
	Regional	5	Friuli-Venezia Giulia, Veneto, Emilia-Romagna, Lombardia, Bolzano
	Local	5	Udine, Mantova, Parma, Verona, Bolzano
Laboratories		1	Brescia IZS
Meat Slaughter Establishments		2	
Processing Establishments		11	

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 five regional offices and five local government offices.

The third involved on-site visits to 13 establishments: two slaughter establishments, and 11 processing establishments. The fourth part involved visit to one government residue and microbiology laboratory, the Instituto Zooprofilattico Sperimentale (IZS) in Brescia, conducting, respectively, 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.

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 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. Italy can use five 75-gram samples to test 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 ß-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 audits of Italy's meat inspection system were conducted in October 2004 and March 2005.

During audit of Italy, conducted by FSIS in October/November 2004, the following deficiencies were identified:

- Two establishments were issued an NOID by the Ministry of Health (MOH) because of SSOP and Sanitation Performance Standards deficiencies.

- In five establishments, the Ministry of Health was not enforcing all of FSIS' inspection requirements.

- Although MOH had audited the two establishments that received the NOIDs, there was no follow-up by MOH to verify that corrective actions had been taken.

- The offices within MOH responsible for audits of meat establishments were not performing a sufficient number of audits of establishments certified for export to the United States.

- Significant deficiencies were noted regarding government oversight of government laboratories, especially in control and supervision.

- The central laboratory in Rome, which is responsible for the control and supervision of the regional laboratories, was not accredited.

- Samples of ready-to-eat products were not being analyzed for both *Listeria monocytogenes* and *Salmonella*.

- In two establishments, implementation of the SSOP with sanitation procedures preventing product contamination was deficient.

- In four establishments, deficiencies in sanitary operations were observed.

- In two establishments, deficiencies in dressing room/lavatories were observed.

- In two establishments, deficiencies regarding equipment and utensils were observed.

- In two establishments, deficiencies in employee hygiene were observed.

- Deficiencies were observed with the use of an incorrect media to test samples for *Listeria monocytogenes*.

All of the deficiencies identified in October/November 2004 had been corrected by the audit in March/May 2005.

During the most recent FSIS audit of Italy, 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 an NOID by the MOH because of SSOP and SPS deficiencies.

- 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*.

- 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.

6. MAIN FINDINGS

6.1 Legislation

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

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 was elevated to the Department level.

6.2.1 CCA Control Systems

Italy's organizational structure has changed since the last FSIS audit in March/May 2005. The office of Veterinary Public Health, Nutrition and Food Safety was elevated to the Department level due to increase of Avian Influenza and other disease conditions. The office of Veterinary Public Health, Nutrition and Food Safety Department now reports directly to the Minister of Health rather than through another department as it did prior to the change. The change provides the department more authority.

The CCA has control over regional and local office activities and also 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. 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

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

- In six establishments, the MOH was not enforcing all of FSIS' inspection 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, local, and in-plant inspection offices at the audited establishments. 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.

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

6.3.1. Audits of Regional and Local Inspection Sites

Five regional offices were audited: Friuli-Venezia Giulia, Veneto, Emilia-Romagna, Lombardia, and Bolzano

Five local offices were audited: Udine, Mantova, Parma, Verona, and Bolzano

No concerns arose as a result of these interviews.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments. Two were pork slaughter establishments, and 11 were pork processing establishments. One establishment received an NOID from the MOH because of SSOP and SPS implementation deficiencies. This establishment 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 Instituto 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 all 13 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In five of the 13 establishments, implementation of the SSOP with sanitation procedures preventing product contamination was deficient.

9.2 SANITATION PERFORMANCE STANDARD

- 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.

9.3 EC Directive 64/433

In eight establishments, the provisions of EC Directive 64/433 were effectively implemented. In the other five establishments, specific deficiencies were identified and 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.

11.1 Humane Handling and Humane Slaughter

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*

Eleven establishments were producing ready-to-eat products for export to the United States. In accordance with FSIS requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

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 13 establishments.

13.2 Testing for *Salmonella* Species

Two establishments 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 required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

Monthly 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 counties 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.

- In six establishments, the MOH was not enforcing all of FSIS' inspection requirements.

14. CLOSING MEETING

A closing meeting was held on December 15, 2005 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. Oto Urban
Senior Program Auditor

Manzoor H. Chaudry

15. ATTACHMENT

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Luigi Ugolotti S.r.i., Prosciutificio di Langhirano, Langhirano, Parma,	11 - 18 - 2005	23 L	Italy
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 23 L

11-18 -05

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/18/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Giuseppe Citterio S.p.A., R H O, Milano, Lombardia,	12 - 06 - 2005	31 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
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11. Maintenance and evaluation of the effectiveness of SSOP's.	
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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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24. Labeling - Net Weights	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 31 L 12-06 -05

10	The product netting used to hang packaged sausage for cooking was contacting the floor. Immediate corrective action was taken by the establishment management to replace contaminated netting and revise the procedures for placing product into the netting 9 CFR 416.13 (c).
38/51/56	The pest management program included the use of poison inside of the facility. Establishment officials removed the poison from inside of the establishment 9 CFR, 416.2(a); EC Directive 64/433, Chapter III 6.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 12/06/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Alcisa S.p.A., Zola Predosa, Bologna, Emilia-Romagna	11 - 23 - 2005	41 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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Part E - Other Requirements	
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37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 41 L 11-23 -05

46/51/56 Product residue from previous operations was observed on the overhead structures (window screen) over the product mixing equipment in the processing room. Corrective action by removing product residues was scheduled by the establishment 9 CFR 416.4 (b); EU Dir.64/433, Chapter III (3).

38/51/56 Spider webs were observed in the corner of the product chilling room # 41. This deficiency was scheduled for immediate correction by the removal of spider webs by the establishment management 9 CFR 416.2(a); Dir.64/433, Chapter III (3)(b).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/23/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fumagalli, Industria Alimentari SpA, Via Briantea, 18, Travernerio (Como), Lombardia	11 - 16 - 2005	92 MS	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 92 MS 11-16 -05

10 Heavily beaded and dripping condensate was observed over a product traffic area and under the refrigeration unit in a fresh meat cooler near exposed fresh product. Immediate corrective action was performed by the establishment employee by removing the condensate 9 CFR 416.13 (c).

41/56 A strong ammonia odor was detected in the pig stunning area. This deficiency was recorded by the inspection service during prior visits and was not completely corrected by the establishment. The establishment was informed about this deficiency by the inspection service, and it was scheduled for corrective action by the establishment 9 CFR 416.2 d; EC Directive 64/433, Chapter I (n).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/16/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Leoncini Prosciutti S.p.A., Via Venezia 204, San Danielle del Friuli, Udine	11 - 09 - 2005	151 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 151 L 11-9-05

46/51/56 Flaking paint was observed over the "product traffic area" in the raw product receiving room and product drying room. The flaking paint was scheduled to be removed prior to operations the following day by the establishment officials 9 CFR (416.4(d)); EC Directive 64/433, Chapter III (a).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/9/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Leoncini S.R.L., Cola' Di Lazise, Verona, Venetto.	11 - 29 - 2005	169 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 169 L 11-29 -05

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/29/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agricola Tre Valli Soc Coop. a.r.l., Villafranca, Verona, Venetto.	11 - 30 - 2005	363 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 363 L 11-30 -05

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/30/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
San Nicola, Prosciuttificio del Sole S.p.A. Ghiare di Corniglio, Parma,	11 - 21 - 2005	498 L	Italy
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Oto Urban	[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 498 L 11-21 -05

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/21/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Recla GMBH-SRL, Zona Vezzano, Silandro, Bolzano.	12 - 01 - 2005	621 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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	O
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

Italy, Est. 621 L 12-01 -05

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

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 12/01/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Martelli F. Iii S.p.A., Dosolo, Mantova, Lombardia	11 - 24 - 2005	643 MS	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	X
59.	

60. Observation of the Establishment

Italy, Est. 643 MS 11-24 -05

10 The conveyor belt used for transporting edible carcass parts in the boning and cutting area was observed to be contaminated with mechanical grease. The establishment removed product and cleaned the belt to correct this deficiency to prevent product contamination. The cause of this deficiency seemed to by mechanical problems and the operation was stopped by the inspection service until mechanical problem was solved 9 CFR 416.13 (c).

10/51 Two conveyor belts used in the boning area for exposed edible product was observed with numerous deep cuts in the surface of the belts. Inspection service scheduled the corrective action by replacing the damaged belts 9 CFR 416.13 (c).

Sanitized equipment in several areas of the establishment (boning and washing rooms) for edible product use was observed with residue from previous days use on the product contact surfaces. This deficiency was corrected in the equipment washing area but was observed in the boning room. Corrective action, by washing and sanitizing equipment again was scheduled by the inspection service 9 CFR 416.13

58 This establishment was issued NOID for SSOP deficiencies,

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/24/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Prosciutte Morgante., Via Aonedis, San Danielle del Friuli, Udine	11 - 14 - 2005	649 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 649 L 11-14-05

10/51 Several holes were observed in the product contact surface of a conveyor belt used for the exposed edible product Corrective action included replacing the damaged belt by the establishment management 9 CFR 416.13 (c).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/14/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Prosciuttificio Di Boschetto s.r.l., Zola Predosa, Bologna, Emilia-Romagna.	12 - 07 - 2005	702 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
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17. The HACCP plan is signed and dated by the responsible establishment individual.	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 702 L 12-07 -05

10/51 Several holes were observed in the product contact surface of a conveyor belt used for exposed edible product. The establishment's corrective action included scheduling and replacement of the damaged belt 9 CFR 416.13 (c).

45/51/56 Container identified for edible product use was being used for inedible product in the slicing room. Corrective action included removing the container was taken by the inspection service 9 CFR, 416.3 (c); EC Directive 64/433, Chapter III 3.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 12/07/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cesepro S.r.l., Via Jacopo Pirona, San Danielle del Friuli, Udine	11 - 09 - 2005	978 L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights.	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 978 L 11-9-05

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 11/09/05