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

AUG 18 2005

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

Dear Dr. Marabelli:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in Italy from March 30 through May 4, 2005. Comments from Italy have been included as an attachment to the 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 email at sally.white@fsis.usda.gov.

Sincerely,

Sally White

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:
Geoffrey Wiggin, Counselor, US Embassy, Rome
Cecilia Piccioni, 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
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Italy Country File—Audit Mar05

FINAL

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

March 30 through May 4, 2005

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 of Ready-to-Eat Products
   - 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* in Raw Product
   - 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 (MOH)
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
RTE	Ready-to-Eat
SSOP	Sanitation Standard Operating Procedure(s)
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Italy from March 30 through May 4, 2005.

An opening meeting was held on March 30, 2005 in Rome with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of Italy's meat inspection system.

The auditors were 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, six regional inspection offices, six local inspection offices, one government residue laboratory, eight government microbiology laboratories performing analytical testing on United States-eligible product, three slaughter establishments, and ten processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Rome
	Regional	6	Tuscany, Friuli-Venezia Giulia, Veneto, Emilia-Romagna, Lombardia, Bolzano
	Local	6	Siena, Udine, Mantova, Parma, Verona, Bolzano
Microbiological Laboratories		8	Brescia IZS, Mantova IZS, Roma IZS, Siena IZS, Modena, IZS, Padova IZS, Cremona IZS, Varese IZS
Residue Laboratories		1	Brescia IZS
Meat Slaughter Establishments		3	
Processing Establishments		10	

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 the regional and local government offices. The third involved on-site visits to 13 establishments: three slaughter establishments, and 10 processing establishments. The fourth part involved visits to one government residue laboratory and eight government microbiology laboratories. The Instituto Zooprofilattico Sperimentale (IZS) in Brescia was conducting analyses of field samples for residues for the establishments certified to export product to the U.S. The Brescia IZS, Mantova IZS, Roma IZS, Siena IZS, Modena IZS, Padova IZS, Cremona IZS, and Varese IZS were conducting analyses of field samples for 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), (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 auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors 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 auditors 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 auditors 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 auditors 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 auditors would audit against any equivalence determinations that have been made by FSIS for Italy under provisions of the Sanitary/Phytosanitary Agreement. The only equivalence determinations that have been made for Italy to date are as follows:

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) products 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

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

The last two FSIS audits of Italy's inspection system identified several problems. All of the deficiencies identified in the April 2003 audit had been corrected by the audit in October/November 2004. These deficiencies included:

- In one establishment, the forefeet of hog carcasses were contacting platforms and employees' boots at the bung dropping and carcass pre-evisceration stations in the slaughter room.

- In one establishment, the overhead rail in the ham washing machine was observed with an accumulation of dried pieces of fat and residue from previous days' operation.

- Percent recovery results for certain chlorinated hydrocarbon compounds fell below the established acceptable limits with no corrective actions taken.

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

- The offices within MOH responsible for audits of meat establishments are 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 the control and supervision area.

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

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

- In five establishments, the MOH was not enforcing FSIS' inspection requirements.

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

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

- In one establishment, deficiencies in establishment grounds and pest control were observed.

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

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

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

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

- In one establishment, the pre-shipment review for sliced ham was being performed with CCPs used from the HACCP program for whole hams.

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

Two establishments were issued a Notice of Intent to Delist (NOID) by the Ministry of Health because of SSOP and Sanitation Performance Standards deficiencies.

6. MAIN FINDINGS

6.1 Legislation

The auditors were 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.

6.2.1 CCA Control Systems

Italy's organizational structure has not changed since the last FSIS audit that was conducted in October/November 2004.

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.

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

The CCA has the ultimate control over all government laboratories.

6.2.3 Assignment of Competent, Qualified Inspectors

The auditors 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 seven establishments, the MOH was not enforcing FSIS' inspection requirements.

6.2.5. Adequate Administrative and Technical Support

- 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*.

6.3 Headquarters Audit

The auditors 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 examination of these documents.

6.3.1. Audits of Regional and Local Inspection Sites

Six regional offices were audited:

- Tuscany
- Friuli-Venezia Giulia
- Veneto
- Emilia-Romagna
- Lombardia
- Bolzano

Six local offices were audited:

- Siena
- Udine
- Mantova
- Parma
- Verona
- Bolzano

No deficiencies were observed.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited three slaughter establishments and 10 processing establishments. Three establishments received an NOID from the MOH because of SSOP and SPS implementation deficiencies. These establishments may retain their 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 government residue laboratory was audited:

- The Instituto Zooprofilattico Sperimentale laboratory in Brescia was conducting analyses of field samples for residues.

No deficiencies were noted.

The following government microbiology laboratories were audited:

- Roma IZS, Siena IZS, Modena IZS, Brescia IZS, Padova IZS, Cremona IZS, Varese IZS, Mantova IZS

- 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*.

9. SANITATION CONTROLS

As stated earlier, FSIS auditors focus on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and 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, and except as noted below, Italy's inspection system had controls in place for light, ventilation, 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 SSOP were met, according to the criteria employed in the U.S. 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 SSOP with sanitation procedures preventing product contamination was deficient.

- In two of the 13 establishments, corrective action to prevent direct product contamination was not effective.

9.2 Sanitation Performance Standards

- In six of the 13 establishments, deficiencies in sanitary operations were observed.

- In one of the 13 establishments, deficiencies in employee hygiene were observed.

- In two of the 13 establishments, deficiencies regarding equipment and utensils were observed.

9.3 EC Directive 64/433

In five establishments, the provisions of EC Directive 64/433 were effectively implemented. In the other eight establishments, deficiencies were identified. Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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 auditors determined that Italy's inspection system had adequate controls in place. No deficiencies were noted.

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 auditors 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 identified regarding humane handling or humane slaughter.

11.2 HACCP Implementation

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

The HACCP programs were reviewed during the on-site audits of the 13 establishments. All establishments had adequately implemented the HACCP requirements. No deficiencies were identified regarding HACCP implementation.

11.3 Testing for Generic *E. coli*

Italy has adopted the FSIS regulatory requirements for testing for generic *E. coli.*

Testing for generic *E. coli* was properly conducted in all of the establishments audited.

11.4 Testing of Ready-to-Eat Products

Ten of the 13 establishments audited 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.

Italy was testing ready-to-eat product for both *Listeria monocytogenes* and *Salmonella* as required by FSIS.

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 auditors reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The government-owned and operated *Instituto Zooprofilattico Sperimentale* of the Ministry of Health 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 2004 was being followed and was on schedule.

12.1 EC Directive 96/22

In the *Instituto Zooprofilattico Sperimentale*, a government residue-testing laboratory located in Brescia, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the *Instituto Zooprofilattico Sperimentale*, a government residue-testing laboratory located in Brescia, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors 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

Italy has adopted the FSIS regulatory requirements for testing for *Salmonella* with the exception of the following equivalent measures:

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 product for *Salmonella*.

Three of the 13 establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in the three establishments in which it was required. No deficiencies were identified 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

During this audit it was found that in all establishments visited, monthly supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place to prevent 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 seven establishments, the MOH was not enforcing FSIS' inspection requirements.

14. CLOSING MEETING

A closing meeting was held on May 4, 2005 in Rome with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
Senior Program Auditor

15. ATTACHMENTS TO THE AUDIT REPORT

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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Industria Prosciutti S.P.A., Langhirano. Emilia-Romagna, Italy	4 – 20 – 05	25L	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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 25L 4-20-05

"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 4-20-05

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), Vennetto, Italy	4 –27 – 05	169L	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 contro' 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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment:	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	0
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	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	X
59.	

60. Observation of the Establishment

Italy, Est. 169L 4-27-05

10/51 Lubricant oil was found on three hams in the receiving cooler. Proper corrective action (trimming) was performed by the establishment officials. There was no procedure for handling this deficiency 9 CFR. 13 (b)(c)

46/56 Non-over product condensation from the cooling unit was observed from the close proximity of product, however in close proximity of stored hams was observed. There was no corrective action during the process of audit 9 CFR 416.4(b); EC Directive 64/433,Chapter III (3).

46/56 In the processing room, one metal form used for forming of ham was observed with big meat particle inside. Immediate corrective action was performed by the establishment officials 9 CFR 416.4(b); EC Directive 64/433, Chapter III (3).

47/51/56 In men's locker room, the separation of street and work clothe was not maintained. Possible cross-contamination was evident 9 CFR 416.5 (b); EC Directive 64/433, Chapter III (3).

58 NOID was issued for SSOP/SPS deficiencies.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
4-27-05

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
Principe di San Daniele S.p.A., San Danielle del Friuli, Udine, Friuli Venezia Giulia, Italy	4 – 7 – 05	205L	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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 205L 4-7-05

"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 4-7-05

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
MEC Carni, Macaria, Mantova, Lombardia, Italy	4 – 13 – 05	304 M/S	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	
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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.	
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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	0
35. Residue	
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	
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.	
59.	

60. Observation of the Establishment

Italy, Est. 304M/S 4-13-05

"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 4-13-05

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
Bertana s.r.l. Castelverde (Cremona), Lombardia, Italy	4 – 21 – 05	312 M/S	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 SSOPs have failed to prevent direct product contamination or adulteration.	X
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	0
35. Residue	
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	
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.	X
59.	

60. Observation of the Establishment

Italy, Est. 312 M/S 4-21-05

10/12/51 Extensive grease contamination observed on the conveyor belt in the boning room. Pork bellies were being contaminated by the grease. The auditor had to point out the problem, and corrective action was not prompt. Part of the corrective action was the proposal to correct the cause of the problem by replacing the roller drum "next year", which the Auditor found to be unacceptable 9 CFR 416.13 (c) & 416.15.

10 Heavily beaded condensate observed over exposed product traffic way in two coolers. A review of records indicated that this has been a problem in the past with no effective corrective action 9 CFR 416.13 (c).

46/56 Racks to hang/transport livers were not cleaned properly and were contaminated with fat particles from previous operations 9 CFR 416.4 (a); EC Directive 64/433, Chapter III (c).

58 Establishment was issued an NOID due to SSOP and SPS deficiencies.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
4-21-05

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
Levoni SpA, San Danielle, Udine, Friuli Venezia Giulia, Italy	4 – 6 – 05	442L	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.	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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11. Maintenance and evaluation of the effectiveness of SSOP's.	
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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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 442L 4-6-05

46/51/56 Excessive hog hair on several dried/cured hams was observed in the drying room. This deficiency was scheduled for correction by the inspection service 9 CFR 416.4 (d)) & 310.18; C/D 64/433 EEC Annex 1 Chapter V (15).

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
4-6-05

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
F.lli Gallo: S.p.A. Langhirano, (Parma), Emilia-Romagna Italy	4 – 22 – 05	586L	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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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 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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 586L 4-22-05

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

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61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4-22-05

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 SILANDRO (BZ) ITALY	04/28/2005	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
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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.	X
13. Daily records document item 10, 11 and 12 above.	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	X
59.	

60. Observation of the Establishment

Italy, Est. 621L 4-28-05

10/12/51	In receiving area, a ham on the conveyor belt was observed with a black speck of extraneous material. Multiple spots of grease were noted on the conveyor belt in the cutting room. In high risk product area an employee was seen picking from the floor a wrapped ham and placing into an edible lug thus contaminating the container to be used for edible product. No immediate corrective actions were taken for the above noted deficiencies during the audit process. 9CFR 416.13(b)(c), 416.15.
45/51/56	Several product trays on the wheeled racks which were ready to be used were observed with holes of varying sizes on the product contact surface. On the conveyor belt in the processing room a hole measuring greater than one inch in diameter was observed posing possible source for product contamination with physical objects. The establishment did not have a plan for maintaining the equipment in good repair. No corrective action was taken for correcting the noted deficiency while the audit was in progress. 9CFR 416.3(a), EC Directive 64/433, Chapter 3(c).
58	NOID was issued to the establishment for above noted deficiencies.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
4-28-05

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
Salumificio Piacenti S.r.L San Gimignano, Tuscany, Italy	4 – 4 – 05	718L	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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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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 718L 4-4-05

46/51/56 Flaking paint over the "product way" area was observed in the processing room. This deficiency was scheduled for correction by the establishment officials 9 CFR (416.4(d)).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

4-4-05

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
Italcarni, Societa Cooperativa Agricola, Migliarina di Carpi, Modena, Italy	4 – 18 – 05	791 M/S	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.	
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	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	()
35. Residue	
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	
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. 791M/S 4-18-05

45/51/56 Rusty areas of the railing system and ceiling of the cooler observed during the operational and pre-operational sanitation. This deficiency was scheduled for correction by the inspection service and establishment officials 9 CFR 416.3 (a); EC Dir. 64/433, Chapter III, 3 (c).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4-18-05

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
Industria Salumi Simonini S.p.a. Castelvetro, Modena, Emilia-Romagna Italy	4 – 19 – 05	946L	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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 946L 4-19-05

10 Frozen product plastic cover was cut exposing product in several cases in the cold storage. Establishment scheduled exposed product to be trimmed.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4-19-05

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
Industria Salumi Faenza, Ravenna, Emilia Romagna, Italy	4 – 15 – 05	972L	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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	0
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	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Italy, Est. 972L 4-15-05

10/51 The conveyor belt used for frozen meat transport was found with engine lubricant on the surface and some areas of the belt were wearing off in the processing room. Establishment and the inspection service performed proper immediate corrective action 9 CFR 416.13 (c).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4-15-05

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
Arienti Sandrino, Traversetolo (Parma), Emilia-Romagna, Italy	4 –26 – 05	1068L	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	X
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	X
57. Monthly Review	
58.	
59	

60. Observation of the Establishment

Italy, Est. 1068L 4-26-05

46/56 Mechanical/lubricant oil was found on the metal frames of the conveyor belt in the product slicing area. This deficiency was corrected immediately by the establishment officials 9 CFR 416.4 (b); EC Dir. 64/433, Chapter III (c).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4-26-05

Ministry of Health
Directorate General
Dept. of Food Nutrition
and Veterinary Health
Office II

July 13, 2005

DGV/IX/25604/P

American Embassy, Rome
Attn. Dr. A. Menghini

Subject: FSIS Final Draft Audit Report conducted from March 30 through May 4, 2005.

We refer to the subject draft and letter transmitting report dated June 10, 2005.

Although we concur with the contents of the above mentioned document, we would appreciate your clarifying the following two points:

- Item 6.2.2., page 9, "Although the MOH had audited the three establishments…." Please indicate to what action this statement refers to.

- Item 7, page 11, the processing establishments were 10 and not 13.

We would very much appreciate it if the Embassy could transmit this letter to Office of International Affairs, FSIS/USDA.

Thank you for your cooperation.

Best regards.

S/d Director General
Romano Marabelli