



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

APR 13 2005

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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:

The Food Safety and Inspection Service (FSIS) has completed an on-site audit of Italy's meat inspection system. The audit was conducted from October 14 through November 17, 2004. Comments from Italy have been included as an attachment to the final audit report. Enclosed is a copy of the final audit report.

If you have questions regarding the audit, you may reach me by telephone at 202-720-3187, by facsimile at 202-690-4040 or electronic mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Geoffrey Wiggin, Counselor, US Embassy, Rome
Cecilia Piccioni, 1st Secretary, Embassy of Italy, Washington
Tony van der haegen, EU Mission to the US, Washington
Norval Francis, Minister/Counselor, US Mission to the EU, Brussels
Barbara Masters, Acting Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA
William James, Deputy Assistant Administrator, OIA
Scott Bleggi, FAS Area Officer
Robert Macke, ITP, FAS
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Amy Winton, State Department
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Italy Country File

FINAL

MAR 22 2005

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

October 14 through November 17, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Ministry of Health; Department General for Food, Nutrition and Public Veterinary Health)
MOH	Ministry of Health
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Lm</i>	<i>Listeria monocytogenes</i>
<i>Salmonella</i>	<i>Salmonella</i> species
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction Systems/Hazard Analysis and Critical Control Points
NOID	Notice of Intent to Delist
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 October 14 through November 17, 2004.

An opening meeting was held on October 14, 2004, in Rome with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit and the auditors' itinerary, 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, Department of Food, Nutrition and Public Veterinary Health) and representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit with a special emphasis on microbiology. 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, six local inspection offices, one government residue laboratory and five government microbiology laboratories performing analytical testing on United States-eligible product, two swine slaughter establishments, and 11 processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Rome
	Regional	5	Tuscany, Friuli- Venezia Giulia, Veneto, Emilia- Romagna, Lombardia
	Local	6	Siena, Udine, Modena, Milan, Parma, Cremona
Laboratories		6	One government residue, five government microbiology
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 on-site visits to 13 establishments: two swine slaughter and 11 processing establishments. The third part involved visits to one government residue laboratory and five government microbiology laboratories, that were, respectively, analyzing field samples for residues and microbiology for the establishments certified to export product to the U.S. The fourth part involved visits to six local inspection offices, five regional inspection offices, and the headquarters of the CCA.

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 and the performance of the microbiology laboratories performing analysis for the U.S. certified establishments.

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 that are safe, unadulterated and properly labeled.

During the opening meeting, the lead 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 auditors would audit the meat inspection system against European Commission Directive 64/433/EC 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 requirements for HACCP, SSOP, and testing for generic *E. coli*, *Salmonella* species, and *Listeria monocytogenes*.

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 government laboratories use ISO 6579 and AOAC 967.25 to analyze for *Salmonella* species.

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.) and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to End), which include the Pathogen Reduction/HACCP regulations.

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

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

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the 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 meat inspection system were conducted in October/November of 2002 and April/May of 2003.

The following deficiencies were observed during the October/November 2002 audit:

- In seven establishments, there were deficiencies with SSOP implementation, maintenance, and record keeping.
- In 11 establishments, deficiencies were noted in the areas of construction and equipment maintenance, sanitary operations, pest control, lighting and water supply.
- In nine establishments, deficiencies were observed regarding HACCP monitoring, verification, corrective actions, and record keeping.
- In five establishments, inspectors did not understand the requirements of PR/HACCP and therefore were not enforcing these requirements.

During the most recent audit of Italy, conducted by FSIS in April/May 2003, the following deficiencies were identified:

- In one establishment, the forefeet of hog carcasses were contacting platforms and employees’ boots at the bung-dropping and carcass pre-evisceration stations.
- In one establishment, the overhead rail in the ham washing machine was observed with an accumulation of dried pieces of fat and soil.
- Percent recovery results for certain chlorinated hydrocarbon compounds fell below the established acceptable limits and no corrective actions were taken.

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

6.2.1 CCA Control Systems

Italy's organizational structure has not changed since the last FSIS audit in April/May 2003.

The CCA has control over regional and local office activities and also has the authority for certifying and decertifying establishments for export to the United States. The CCA is responsible for carrying out inspections of individual establishments and for approving and withdrawing the eligibility of individual establishments. The CCA was testing for *Listeria monocytogenes* and *Salmonella* species on product, and had conducted verifications of those certified establishments in which product had been tested positive for *Lm* and of those establishments that had received Notices of Intent to Delist during the last FSIS audit.

6.2.2 Ultimate Control and Supervision

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

Although the Ministry of Health (MOH) had audited the two establishments that received the NOIDs, there was no follow-up by the MOH to verify that corrective actions had been taken. In addition, the offices within the MOH responsible for audits of meat establishments were not performing a sufficient number of audits of establishments certified for export to the United States.

The CCA has the ultimate control over all government laboratories. The following deficiencies were found.

- Significant deficiencies were noted regarding government oversight of government laboratories, especially regarding control and supervision.
- Samples of ready-to-eat products were not being analyzed for both *Listeria monocytogenes* and *Salmonella* species.

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

The MOH has the authority and responsibility to enforce the laws. The following deficiencies were noted.

- In five establishments, the MOH was not enforcing FSIS's inspection requirements.
- Although the MOH had audited the two establishments that had received the NOIDs, there had been no follow-up audits by the MOH to verify that corrective actions had been taken.

6.2.5 Adequate Administrative and Technical Support

No deficiencies were identified.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents in the headquarters, regional, local, and in-plant inspection offices. 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;
- Label approval records such as generic labels, and animal raising claims;
- 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;
- Export product inspection and control including export certificates, and
- Enforcement actions.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments. Two were swine slaughter and 11 were processing establishments. None of the 13 establishments was delisted. Two establishments received a Notice of Intent to Delist (NOID) from the MOH because of SSOP and SPS implementation deficiencies. 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.

The following residue laboratory was reviewed:

- The Istituto Zooprofilattico Sperimentale (IZS), a government laboratory located in Brescia, was conducting analyses of field samples for residues.

No deficiencies were noted.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs. If private laboratories are used to test United States samples, the auditors evaluate compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following microbiology laboratories were reviewed. These laboratories were conducting analyses of field samples for *Listeria monocytogenes* and *Salmonella*.

- IZS, Teramo
- IZS, Brescia
- IZS, Pordenone
- IZS, Mantova
- IZS, Parma

The following deficiencies were noted.

- Central government oversight of the government laboratories was deficient, especially regarding control and supervision of the regional laboratories.
- The central laboratory in Rome, which is currently responsible for oversight of the other government laboratories, is not accredited.
- Samples of ready-to-eat products were not being analyzed for both *Listeria monocytogenes* and *Salmonella*.
- An incorrect media was being used to test samples for *Listeria monocytogenes*.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor reviews 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, and except as noted below, Italy's inspection system had controls in place for SSOP programs, the prevention of actual or potential instances of product cross-contamination, and good product handling and storage practices.

In addition, Italy's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, light, ventilation, plumbing and sewage, water supply, ante-mortem facilities, outside premises, 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 two establishments, implementation of SSOP to prevent product contamination was deficient.

9.2 EC Directive 64/433

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

- In one establishment, deficiencies in establishment grounds and pest control were observed.
- In two establishments, deficiencies in dressing rooms/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.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, 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

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

11.3 Testing for Generic *E. coli*

No deficiencies were identified regarding the testing program for generic *E. coli*.

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 *Lm* 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 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 *Instituto Zooprofilattico Sperimentale (IZS)*, a government 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 (IZS)*, 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 (IZS)*, 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 measure:

- The government laboratories use ISO 6579 and AOAC 967.25 to analyze for *Salmonella*.

Two establishments were required to test for *Salmonella* in raw product. No deficiencies were identified regarding the testing program for *Salmonella* in raw product.

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 13 establishments, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for the prevention of commingling of product intended for export to the United States with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

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

- In five establishments, the Ministry of Health was not enforcing FSIS's inspection requirements.
- In two establishments, the MOH had found deficiencies through their audit process, but had not verified that corrective actions had been taken.

14. CLOSING MEETING

A closing meeting was held on November 17, 2004, in Rome with the CCA. In this meeting, the preliminary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
International Audit Staff Officer



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Individual Foreign Laboratory Form—Residue Laboratory
Foreign Country Response to Draft Final Audit Report

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 11/03/2004

NAME OF FOREIGN LABORATORY
 Istituto Zooprofilattico Sperimentale
 Della Lombardia e Della Emilia Romagna

FOREIGN GOVT AGENCY
 Dipartimento Alimenti e Sicurezza

CITY & COUNTRY
 Brescia, Italy

ADDRESS OF LABORATORY
 Via Bianchi n. 719
 25124 Brescia, Lombardia, Italy

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
 Dr. Roberto Piro, Head of the Residue Dept., Dr. Filippo Castoldi, Regional Office

Residue Code/Name			100	111	200	203	300	400	500	800	923	950	SV	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A	A	A	A	A	A	N	N	N
	Sample Frequency	02		A	A	A	A	A	A	A	A	N	N	N
	Timely Analysis	03		A	A	A	A	A	A	A	A	N	N	N
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O
Data Reporting	06	A	A	A	A	A	A	A	A	A	N	N	N	
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	N	N	N
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	N	N	N
	Equipment Operation	09		A	A	A	A	A	A	A	A	N	N	N
	Instrument Printouts	10		A	A	A	A	A	A	A	A	N	N	N
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	N	N	N
	Recovery Frequency	12		A	A	A	A	A	A	A	A	N	N	N
	Percent Recovery	13		A	A	A	A	A	A	A	A	N	N	N
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	N	N	N
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A	A	N	N	N
	Corrective Actions	16		A	A	A	A	A	A	A	A	N	N	N
International Check Samples	17	A	A	A	A	A	A	A	A	A	N	N	N	
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	O	O	O	O	O	O	O	N	N	N
OTHER REVIEW		19	EVAL. CODE											
		20												

Signature of reviewer *J. Bolstad MW for Oto Urban DVM*

Date *November 30, 2004*

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 11/03/2004	NAME OF FOREIGN LABORATORY Istituto Zooprofilattico Sperimentale Della Lombardia e Della Emilia Romagna
FOREIGN GOV'T AGENCY Dipartimento Alimenti e Sicurezza	CITY & COUNTRY Brescia, Italy		ADDRESS OF LABORATORY Via Bianchi n. 719 25124 Brescia, Lombardia, Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Roberto Piro, Head of the Residue Dept., Dr. Filippo Castoldi, Regional Office		

RESIDUE	ITEM NO.	COMMENTS
		N = not reviewed at this time.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Principe di San Daniele S.p.A., San Danielle del Friuli, Udine, Friuli Venezia Giulia, Italy	2. AUDIT DATE 10-21-04	3. ESTABLISHMENT NO. 205L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	X
		45. Equipment and Utensils	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	X
18. Monitoring of HACCP plan.		47. Employee Hygiene	
19. Verification and validation of HACCP plan.		48. Condemned Product Control	
20. Corrective action written in HACCP plan.		Part F - Inspection Requirements	
21. Reassessed adequacy of the HACCP plan.		49. Government Staffing	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	50. Daily Inspection Coverage	
Part C - Economic / Wholesomeness		51. Enforcement	X
23. Labeling - Product Standards		52. Humane Handling	0
24. Labeling - Net Weights		53. Animal Identification	0
25. General Labeling		54. Ante Mortem Inspection	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		55. Post Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		Part G - Other Regulatory Oversight Requirements	
27. Written Procedures	0	56. European Community Directives	X
28. Sample Collection/Analysis	0	57. Monthly Review	
29. Records	0	58.	
Salmonella Performance Standards - Basic Requirements		59.	
30. Corrective Actions	0		
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 205L 10-21-04

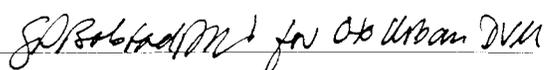
- 22/51 The establishment was using the critical limits for whole hams when performing the pre-shipment reviews for sliced prosciutto ham; documentation of these improper pre-shipment reviews was also attached to U.S. export certificates. Prompt corrective action was scheduled. [Regulatory reference: 9CFR 417.5(c)]
- 44/51/56 A broken waste receptacle was observed in the ham-salting area. The establishment management corrected this immediately. [9CFR 416.2(h)(3); C/D 64/433 EEC Annex 1, Chapter III(3)(c)]
- 45/51/56 Plastic containers were being used for both edible and inedible product and were not clearly marked according to their intended use. A metal container used for inedible salt was also not marked according to its intended use. The establishment management took no immediate corrective actions; the MOH inspection official ordered corrections. [9CFR 416.3(c); C/D 64/433 EEC Annex 1, Chapter III(4)]
- 46/56 Heavy, dripping condensation was observed directly over the prosciutto boning line following a lunch break. The establishment management took no immediate corrective actions until ordered to do so by the MOH officials. [9CFR 416.4(d); C/D 64/433 EEC Annex 1, Chapter III(3)]
- 46/51/56 The water temperature in a sterilizer in the boning room was 76°C; a water temperature of 82°C is required.

Following the audit, the MOH officials issued to the establishment management a Notice of Intent to Delist if adequate actions to correct the HACCP and SSOP implementation deficiencies are not taken within 30 days of this audit.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 for Oto Urban DVM Oct. 21, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION MEC Carni, Macaria, Mantova, Lombardia, Italy	2. AUDIT DATE 11-10-04	3. ESTABLISHMENT NO. 304 M/S	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Italy, Est. 304M/S 11-10-04

- 10 Fresh meat was contacting the floor in the receiving cooler. This was corrected by the establishment management officials. [Regulatory reference: 9CFR 416.13]
- 10/51 (A) An employee was observed to contaminate his hands by contacting the floor and a waste receptacle and subsequently handling edible-product without washing his hands. This was not corrected immediately, either by the establishment management or by the MOH officials. [9CFR 416.13]
- (B) An exposed ham was contaminated through contact with a cart. This was not corrected immediately, either by the establishment management or by the MOH officials. [9CFR 416.13]
- (C) The electric cord for the carcass-splitting saw was contacting the floor and subsequently the passing carcasses. The MOH officials took immediate corrective actions. [9CFR 416.13]
- 45/56 An edible product container was observed on the floor in the boning room. An establishment employee corrected this immediately. [9CFR 416.3(c); C/D 64/433 EEC Annex 1, Chapter III, 3(c)]

Following the audit, the MOH officials issued to the establishment management a Notice of Intent to Delist if adequate actions to correct the HACCP and SSOP implementation deficiencies are not taken within 30 days of this audit.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 for Oto Urban DVM Nov. 10, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agricola Tre Valli soc. coop. a r.l. Villafranca, Verona, Venetto, Italy	2. AUDIT DATE 10-28-04	3. ESTABLISHMENT NO. 363L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use 0 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		0
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue		0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements		
10. Implementation of SSOP's, including monitoring of implementation.		X	36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import		
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan.			41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
18. Monitoring of HACCP plan.			46. Sanitary Operations		
19. Verification and validation of HACCP plan.			47. Employee Hygiene		
20. Corrective action written in HACCP plan.			48. Condemned Product Control		
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		X
24. Labeling - Net Weights			52. Humane Handling		0
25. General Labeling			53. Animal Identification		0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection		0
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		0
27. Written Procedures		0	Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis		0	56. European Community Directives		
29. Records		0	57. Monthly Review		
Salmonella Performance Standards - Basic Requirements			58.		
30. Corrective Actions		0	59.		
31. Reassessment		0			
32. Written Assurance		0			

60. Observation of the Establishment

Italy, Est. 363L 10-28-04

10/51 Grease stains were observed on three fresh hams that had passed the inspection point. The establishment officials took corrective actions. [Regulatory reference: 9CFR 416.13c]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Oto Urban for Dr. Oto Urban DVM Oct. 28, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Salumificio Brianteo S.p.A. Garbagnate Monastero, Lecce, Lombardia, Italy	2. AUDIT DATE 11-2-04	3. ESTABLISHMENT NO. 482L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 482L 11-2-04

No comments were necessary.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

J.P. Bolstad (W) for Oto Urban DVM Nov. 2, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Martelli S.p.A., Dosolo, Mantova, Lombardia, Italy	2. AUDIT DATE 11-8-04	3. ESTABLISHMENT NO. 643 M/S	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP			33. Scheduled Sample	
8. Records documenting implementation.			34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.			36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light	
14. Developed and implemented a written HACCP plan .			41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils	
18. Monitoring of HACCP plan.			46. Sanitary Operations	X
19. Verification and validation of HACCP plan.			47. Employee Hygiene	
20. Corrective action written in HACCP plan.			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards			51. Enforcement	X
24. Labeling - Net Weights			52. Humane Handling	
25. General Labeling			53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection	X
27. Written Procedures			Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis			56. European Community Directives	X
29. Records			57. Monthly Review	
Salmonella Performance Standards - Basic Requirements			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Italy, Est. 643M/S 11-8-04

46/51/56 An old, loose piece of plastic tape was observed over an edible fat container. The establishment officials scheduled prompt correction. [Regulatory reference: 9CFR 416.4(d); C/D 64/433 EEC Annex 1, Chapter III]

51/55 Hair was observed on three hams in the cooler and the boning room. The MOH officials took corrective actions. [9CFR 310.18]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

J.P. Bobsted M for Oto Urban DVM Nov. 8, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rovagnati S.p.A, Biassono, Milan, Lombardia, Italy	2. AUDIT DATE 11-5-04	3. ESTABLISHMENT NO. 508L	4. NAME OF COUNTRY Italy
		5. NAME OF AUDITOR(S) Dr. Oto Urban	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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 SSOPs 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	X
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	X
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 508L 11-5-04

47/56 An edible-product employee was observed to contaminate his mesh glove by contacting the floor and a metal stand that was contacting the floor without subsequently washing and sanitizing his hands and the glove. The MOH officials ordered correction. [Regulatory reference: 9CFR 416.5(a); C/D 64/433 EEC Annex 1, Chapter III(3)]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

SD (Balstedt) for Oto Urban DVM Nov. 5, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Prosciuttificio Di Boschetto, Sala Baganza, Parma, Emilia Romagna, Italy	2. AUDIT DATE 11-9-04	3. ESTABLISHMENT NO. 702L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	0
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 702L 11-9-04

No comments were necessary.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

J. Robstad (M) for Oto Urban DVM Nov. 9, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Effe S.p.A., Lesignano Bagni, Parma Emilia Romagna, Italy	2. AUDIT DATE 11-4-04	3. ESTABLISHMENT NO. 713L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 713L 11-4-04

No comments were necessary.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Oto Urban for Oto Urban DVM Nov. 4, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Salumificio Piacenti S.r.L. San Gimignano, Tuscany, Italy	2. AUDIT DATE 10-18-04	3. ESTABLISHMENT NO. 718L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	X
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 718L 10-18-04

38/56 Flies were observed in the processing area. The establishment officials took immediate corrective actions. [Regulatory reference: 9CFR 416.2(a); C/D 64/433 EEC Annex 1, Chapter III(3)(b)]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

J. Bobstad MW for Oto Urban DM Oct. 18, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION A & B Prosciutti Service, San Danielle, Udine, Friuli Venezia Giulia, Italy	2. AUDIT DATE 10-21-04	3. ESTABLISHMENT NO. 720L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	X
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	X
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 720L 10-21-04

44/51/56 A broken waste receptacle was observed in the ham-salting area. The establishment management corrected this immediately. [Regulatory reference: 9CFR 416.2(h)(3); C/D 64/433 EEC Annex 1, Chapter III(3)(c)]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Oto Urban, DVM Oct. 21, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Parmacotto s.p.a. Sala Vitale Baganza, Parma, Emilia Romagna, Italy	2. AUDIT DATE 11-4-04	3. ESTABLISHMENT NO. 744L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	X
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	X
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 744L 11-4-04

47/56 An edible-product employee contaminated his hands by contacting a waste receptacle and continued to work with product-contact surfaces without washing his hands. [Regulatory reference: 9CFR 416.5(a)(3); C/D 64/433 EEC Annex 1, Chapter III(3)]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

JR Bolstad for Oto Urban, DVM Nov. 4, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Industria Salumi Simonini S.p.a. Castelvetro, Modena, Emilia-Romagna Italy	2. AUDIT DATE 10-26-04	3. ESTABLISHMENT NO. 946L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	X
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 946L 10-26-04

46/56 Condensation was observed directly above exposed product in the meat receiving cooler. The establishment management took immediate corrective actions. [Regulatory reference: 9CFR 416.4(b); C/D 64/433 EEC Annex 1, Chapter III(3)]

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Roberto M. for Oto Urban DVM Oct. 26, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Schianchi & C. S.r.L. Langhirano, Parma, Emilia-Romagna, Italy	2. AUDIT DATE 10-29-04	3. ESTABLISHMENT NO. 1226L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	0
27. Written Procedures	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Italy, Est. 1226L 10-29-04

No comments were necessary.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Oto Urban for Oto Urban *Oct. 29, 2004*

seal/

MINISTRY OF HEALTH

Department of Prevention and Communication
General Office of Veterinary Health and Food Products
Office no. IX

Dr. Sally White
Director, International Equivalence Staff
Office of International Affairs
United States Department of Agriculture

Embassy of the United States of America
Rome – Fax 06 4788 7008

DOVA / IX / 8894 / P March 10, 2005

Re: FSIS Draft Final Report of a meat inspection system audit conducted in Italy from October 14 through November 17, 2004

This document refers to the letter of January 12, 2005 which accompanied a draft of the report on the inspection mission conducted in Italy from October 14 through November 17, 2004.

On November 17, 2004 the final meeting with the American inspection team was held at the office of the writer of this document. The American team was hired to conduct a series of audits at the offices of control of the plants that exports products based on meat to the United States and at the plants themselves. During the course of these meetings it emerged that for two plants the American inspector asked to send the “thirty-day letter,” that is, a promise to provide assurances on the remedy of all the irregularities found.

Plant 205 L Principe di San Daniele

a) During the course of the inspection conducted on October 21, 2004 by Dr. O. Urban at a plant that produces products based on meat, several instances of non-compliance were found and for which it was requested that assurances be provided on the remedy of all the irregularities indicated and discussed during the final meeting.

- The presence of condensation in the plant under discussion. A failure to take immediate measures.
- Pre-shipment review to be modified according to the finished product
- Incorrect identification color of several utensils
- Temperature for the sterilization of the deboning knives not in accordance with regulations
- Scale plate is cracked →
- A container for overflow paper does not work
- The method of recording thermometer calibrations in the procedures in the HACCP manual →
- Temperature in the deboning area is not in accordance with regulations. →

b) measures adopted

On November 14, 2004 this General Office conducted an inspection at the same plant in order to verify that the irregularities indicated by the American inspector had been corrected. During the course of this inspection it was found that all the irregularities indicated had been corrected.

In a letter sent by this Ministry on November 26, 2004 addressed to the Company that owns the plant, the Health Inspector for the Region and Veterinary Services, the irregularities were cited, together with a demand for the immediate resolution and also for the purposes of a more detailed evaluation of the history of the plant over the years, the following documentation was requested:

- A copy of all the irregularity forms compiled by the official veterinarian for the years 2002 – 2003 – 2004.
- A copy of all the irregularity forms compiled by the veterinarian supervisor for the years indicated above.
- A copy of the inspection report prepared by the inspection office of the Regional Veterinary Service in the years indicated above and any measures and acts intended to verify conformity with U.S. regulations.
- A copy of all the communications sent by the company for the purposes of settling the irregularities.

In addition, in the same letter there was a communication that the company was placed in an intensified program of inspections on the part of the Ministry author of this document.

The analysis of the documentation caused this office to issue a *Letter of January 17, 2005* to the regional and local oversight offices in which it demands that only official or supervisory veterinarians be assigned to the plants that manufacture products based on meat for the purposes of export to the United States of America. These official or supervisory veterinarians must have proven technical – practical training on the requirements and the standards established by the laws of the United States. It was also demanded that, in more general terms, the company moved towards the timely adoption of the necessary measures to prevent the repetition of the irregularities and the failure to observe the current laws, or if this is not done the removal of the plant from the list of plants that export to the United States.

In letter no. 2700/spe/vet.6 of February 3, 2005, the Regional Inspection Office of Friuli V.G. communicated that on February 2, 2005, at the Veterinary Office of the ASL of San Daniele there was a meeting to make the point on the organization of veterinary controls on the plants in San Daniele dei Friuli that export to the United States. During the course of the meeting, Dr. R. Coassin, the director of the Veterinary Office of the Friuli Region V.G., pointed out the need to follow up the recommendations expressed by this Ministry of Health in the letter of January 17, 2005. At the conclusion of this meeting the new organization of control activities was formalized. The new organization assigned the task to an official veterinarian who would perform the activities of supervisor or coordinator of the team of official veterinarian controllers for the U.S. plants, and the scheduling of their oversight activities.

XS

Plant 304L MFC Carol

During the course of the inspection visit conducted by Dr. O. Urban on November 10, 2004 at an slaughterhouse plant authorized for the provision of raw material for the production of products based on meat destined for export to the United States, several irregularities were found:

- In a refrigeration cell several pieces of meat hooked to carts were touching the floor;
- Several containers (barrels) in plastic material while clean were not identified in respect to their intended use;
- In the cutting room, during the course of the inspection, an operator in charge of the transport of the carts of fresh meat noticed that a piece of meat fell on the floor. This employee picked it up and deposited it in a special container and subsequently continued with the transfer of the meat to the destination area without having washed his hands;
- Several knives that had undergone washing procedures and intended for use for the deposit of fresh meat had not been perfectly cleaned (the presence of pieces of fat). —

For this plant there was a demand for assurances on the correction of the irregularities found during the course of the inspection visit.

In light of the results of the inspection, this Ministry, in a letter sent on November 26, 2004 to the Company, the Health Inspector for the Region and Veterinary Services, in the same manner as had been done for Plant 205L and for the same reasons, the following documentation was requested.

- A copy of all the irregularity forms compiled by the official veterinarian for the years 2002 – 2003 – 2004.
- A copy of all the irregularity forms compiled by the veterinarian supervisor for the years indicated above.
- A copy of the inspection report prepared by the inspection office of the Regional Veterinary Service in the years indicated above and any measures and acts intended to verify conformity with U.S. regulations.
- A copy of all the communications sent by the company for the purposes of settling the irregularities discussed in points 1-3.

This documentation arrived at these General Offices on December 16, 2004.

On December 14, 2004 these General Offices performed an inspection at the plant in question for the purposes of verifying that the irregularities shown on the American inspection had been corrected.

During the course of the Ministry inspection, it was found that all the irregularities shown on the American inspection had been corrected. Nevertheless, it was shown that the procedures have been established correctly but that their application is still lacking.

In light of the above, in a letter of January 12, 2005 these General Offices communicated to the Regional Inspection Office and Veterinary Services that for the plants involved in export to the United, the controls must be reinforced and for this reason, that only official or supervisory veterinarians be assigned to the plants that manufacture products based on meat for the purposes of export to the United States of America. These official or supervisory veterinarians must have proven technical – practical training and experience on the requirements and the standards established by the laws of the United States. The failure to comply with these requirements may threaten the continued presence of the plant on the list of United States plants. The plant must also be proactive in respect to irregularities found in the plant itself.

In light of the above, there is a current movement towards the reorganization of veterinary controls in the areas of competence in the Lombardy region that oversee plants that export to the United States. In addition, since it was included in an intensified inspection program, this General Office has planned another inspection for March 22, 2005 at plant 304 M/S in order to verify compliance and the correct application of the standards required by United States regulations.

The Lombardy region will communicate to the Ministry that has prepared this document concerning the new organization of official control and supervision in the plant in question.

It is hereby declared that the Office that prepared this document has taken into consideration the observations presented in the PSIS inspection report and as we have had the occasion to communicate, during meetings and teleconferences, we have adopted the most suitable measures to prevent the repetition of unfavorable inspection situations in the plants.

We thank you and remain at your disposal for any further clarifications.

The Director General

/signature: R. Marabelli/