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

FEB 05 2010

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

Dear Dr. Borrello:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Italy's meat inspection system August 26 to September 29, 2009. Comments received from the government of Italy have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

James Dever, Minister-Counselor, US Embassy, Rome
Maria Trinchieri, Commercial Attaché, Embassy of Italy
Canice Nolan, First Secretary, EU Mission to the US, Washington
Debra Henke, Minister-Counselor, US Mission to the EU, Brussels
Bernard Van Goethem, Director, Directorate E, European Commission, Brussels
Ghislain MARECHAL, EC - DG SANCO - International questions (bilateral)"
Alfred Almanza, Administrator, FSIS
Lisa Wallenda Picard, OA, FSIS
Ronald Jones, Acting Assistant Administrator, OIA
Philip Derfler, Assistant Administrator, OPPD
Dan Engeljohn, Deputy Assistant Administrator, OPPD
Ann Ryan, EB, State
David Young, FAS Area Director, FAS
James Adams, Director, IAS, OIA
Andreas Keller, Director, IES, OIA
Rick Harries, Director, EPD, OIA
Jerry Elliott, Director, IID, OIA
Stephen Hawkins, FSIS Codex Programs Staff, OIA
Harry Walker ,IES, OIA
Office of Science and Technical Affairs, FAS
Country File

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

AUGUST 26 THROUGH SEPTEMBER 29, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

ASL	Local Health Units (*Azienda Sanitara Locale*)
CCA	Central Competent Authority, Ministry of Health
DVPHNFD	Department of Veterinary Public Health, Nutrition, and Food Safety
DGSAN	General Directorate for Food Safety and Nutrition
EC	European Commission
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
IZS	Zooprophylactic Experimental Institute (*Istituto Zooprofilattico Sperimentale)*
MOH	Ministry of Health
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point (Programs)
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOPs	Sanitation Standard Operating Procedures
VIC	Veterinarian-in-Charge

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Italy from August 26 through September 29, 2009. This was a routine audit with special emphases on government oversight, humane handling and slaughter of livestock, daily inspection, microbiological testing programs, and corrective actions taken in response to (1) two establishments that were delisted during the previous FSIS audit and subsequently re-listed, (2) an establishment that received a Notice of Intent to Delist (NOID) during the previous audit, and (3) an establishment that was audited by APHIS, with concerns shared with FSIS. Italy is eligible to export pork and pork products to the United States. Between January 1 and August 31, 2009, Italy exported 5,053,995 pounds of meat products to the United States, of which 590,532 pounds were reinspected at US ports of entry (POE). A total of 39 pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during March-April 2008 resulted in restrictions of the abilities of three establishments in Italy to export meat products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		08/26-09/29, 2009	03/26-04/25, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	2	3
	Local	1	3
	Establishment Level	14	11
Laboratories Audited			
	Microbiology	0	1
	Residue	0	0
Establishments Audited			
	Slaughter/processing	2	2
	Processing	12	9
Enforcement Actions Initiated			
	NOID	0	1
	Delistment	0	2
Risk Area Findings		(14 Ests. audited)	(11 Ests. audited)
	Sanitation Controls (SSOPS, SPS)	3	20
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	10	0
	Residue Controls	0	0
	Microbiology Controls	0	0
	Inspection/Enforcement Controls	10 (71.4%)	9 (81.8%)
	Special Emphasis (HH, O157:H7)	0	0

1.3 Summary Comments for the Current Audit

Improvement was noted in nearly all areas, the exception being HACCP non-compliances reported in ten establishments; however, nine of these were attributable to minor record-keeping details, and one was an inadequate description a verification activity in the written HACCP plan (the activity was actually being performed and documented). All non-compliances identified during the previous FSIS audit had been addressed and corrected. There were no repeat non-conformances.

2. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture conducted an audit of Italy's meat inspection system on August 26 through September 29, 2009.

An opening meeting was held on August 26 in Rome with the Central Competent Authority (CCA) – the Department of Veterinary Public Health, Nutrition, and Food Safety, which is one of four departments under the Ministry of Health (MOH). In this meeting, the auditor confirmed the objective and scope of the audit and the auditor's itinerary and requested additional information needed to complete the audit of Italy's meat inspection system.

Representatives from MOH headquarters and representatives from its regional and local inspection offices accompanied the auditor during each audit activity.

3. OBJECTIVES OF THE AUDIT

The objectives were (1) to determine whether the concerns identified during the 2008 audit had been appropriately addressed and (2) to evaluate the performance of the MOH with respect to government oversight and enforcement of the Italian and FSIS regulatory requirements relative to maintaining an inspection system equivalent to that of the United States. This included the following areas of special emphasis:

- The effectiveness of corrective actions taken regarding non-compliances reported during the previous FSIS audit
- Government oversight
- Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) Requirements
- Humane handling and slaughter of livestock
- Controls for microbiological testing of ready-to-eat (RTE) products and carcasses
- Daily inspection
- Payment of inspectors
- The CCA's oversight of slaughter establishments' implementation of controls to prevent contamination of carcasses with feces or ingesta
- Field inspection personnel's knowledge and application of the FSIS regulatory requirements

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with inspection officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records and personnel interviews in the country's inspection headquarters and in two regional and one local inspection offices. The third part involved on-site visits to 14 slaughter-and-processing establishments.

Thirteen establishments were selected randomly: 005L, 0163L, 0167L, 0169L, 0348L, 0478L, 0508L, 0621L, 0643MS, 0720L, 0791MS, 0972L, and 1249L. Est. 718L had been delisted during the previous audit; Italy provided written corrective actions taken and on the basis of these, FSIS granted Italy's request to re-list it, and it was added to this current audit itinerary. Also, FSIS was notified, on July 9, 2009, that a recent visit to Italy by APHIS (on May 27, 2009), including a visit to Est. 167L on June 8, 2009, resulted in concerns regarding the state of sanitary conditions at this establishment. Consequently, this establishment was added to the itinerary in lieu of Est. 335L, which had been randomly selected and was in close proximity to Est. 167L.

Program effectiveness determinations of Italy's inspection system focused on five areas of government controls and oversight and five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and a testing program for *Enterobacteriaceae* and Total Viable Count, which has been accepted by FSIS as equivalent in European Community Member States in lieu of testing for generic *Escherichia coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species.

During the establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection activities are carried out by the inspection officials and determined if controls were in place to ensure that the production of meat and meat products were safe, unadulterated and properly labeled.

In the opening meeting, the auditor explained that Italy's meat inspection system would be audited against the following standards: (1) FSIS regulatory requirements, as applicable, (2) Italian requirements specific to exporting meat and meat products to the US, and (3) FSIS equivalence determinations specific to Italy. FSIS requirements include, among other things, daily inspection in all applicable certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts thereof, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOPS, and testing programs for *Enterobacteriaceae* and *Salmonella* species.

The following FSIS equivalence determinations have been made for Italy under the provisions of the World Trade Organization Sanitary/Phytosanitary Agreement:

- Testing for *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU Member States exporting meat products to the United States.
- Government laboratories use ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella*.
- Italy uses five 75-gram samples for testing of Ready-To-Eat (RTE) product for *Salmonella*.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of US 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 PR/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 B-agonists

6. SUMMARY OF THE PREVIOUS TWO FSIS AUDITS

Final audit reports are available on FSIS' website at:
http://www.fsis.usda.gov/regulations/Foreign_Audit_Reports/index.asp.

March-April 2008

Eleven of the 95 certified establishments, three Regional offices, three local offices, and one microbiology laboratory were audited. The following non-compliances were reported:

- Non-conformances regarding enforcement of some aspects of FSIS regulatory requirements that should have been identified in advance by inspection officials were reported in nine of the eleven establishments audited.

- Two establishments were delisted. (At the request of the MOH, and at the direction of the Director, IAS, one establishment was re-visited by the auditor on May 2, 2008, to assess the status of corrective actions and, after consultation with the Director, was re-listed the same day. The other establishment was re-listed by FSIS in February 2009 on the basis of written reports by the MOH of corrective actions taken.)
- One establishment received a NOID by the CCA due to multiple pre-operational sanitation non-conformances, grease smudges on carcasses and hams, and neglected maintenance and cleaning in the inedible shipping area.
- Twenty sanitation non-compliances were reported.
- Labeling non-compliance was reported in one establishment..

February-March 2007

Eight of the 95 certified establishments, one Regional office, one local office, and one microbiology and residue laboratory were audited; there were no delistments one establishment received a NOID due to SSOP and SPS non-compliances. The following were reported:

- Non-conformances regarding enforcement of some aspects of FSIS regulatory requirements that should have been identified in advance by inspection officials were reported in seven of the eight establishments audited.
- Sixteen incidents of sanitation non-compliance were reported.

7.2 Government Oversight

7.2.1 CCA Control Systems

Oversight of Italy's meat inspection system is provided by the Department of Veterinary Public Health, Nutrition, and Food Safety (DVPHNFD), which is one of four Departments under the MOH. The DVPHNFD is further divided into three branches, which include two General Directorates, one of which now contains the Office of the Secretariat, which is responsible for food-related risk assessment (this is a change since the last FSIS audit; previously, the Office of the Secretariat was a third branch). Of the two General Directorates, the General Directorate for Food Safety and Nutrition (DGSAN) is the entity which is predominantly responsible for the enforcement those requirements which are of interest to FSIS. This General Directorate provides oversight to nine offices addressing products of animal origin and the export of food products. Office IX (Foodstuffs Export) is responsible for the export of meat products to the United States.

Within the MOH's Department of Veterinary Health, there are three Units. Unit I is the Office of General Affairs. Unit II provides direct oversight of the microbiology laboratories; all microbiology laboratories employed for analysis of US-eligible products are government-owned and -operated. Unit II conducts research coordination and

experimentation by the Zooprophylactic Experimental Institute (*Istituto Zooprofilattico Sperimentale,* IZS) and training coordination. Unit III is the Office of International Relations and International Epidemiology ad international epidemiology.

Ultimate control of establishments certified to export to the United States is achieved through two intermediate levels. Oversight provided by the Central Competent Authority through 21 second-level Regional Health Service offices (19 regional and two autonomous provincial offices—Trento and Bolzano; hereinafter, the terms "Region" and "Regional offices" will include the two Autonomous Provinces); their responsibilities include planning, coordination, guidance, authorization of establishments to operate, and verification of controls by the Local Health Units (see below). Each Regional office has a number of third-level Local Health Units, or "*Azienda Sanitara Locale*" (ASLs); there are a total of 195 ASLs. Each Region in Italy has a Directorate or an equivalent public sanitation authority, who oversees a number of ASLs in the area (the number of ASLs varies—each autonomous province has one ASL; each region has more than one). The ASLs are responsible, at the local level, for the organization and management of all public health services. The establishments certified to export to the United States are overseen by these ASLs, and the assigned veterinarians (designated as Official Veterinarians) are paid directly by the ASLs (this has not changed since the last FSIS audit). There are two Services within the ASLs, the Food Hygiene and Nutrition Service and the Local Veterinary Services; the latter are responsible for animal health (Area A), inspection and control of foods of animal origin (Area B), and animal welfare, hygiene of animal husbandry and of farming production (Area C).

Headquarters officials are paid directly by the Ministry of Economics and Finance. Regional veterinarians are paid by the regional administrations and the officials in the ASLs are paid by the ASL administrations; both out of funds also provided by the Ministry of Economics and Finance. The Ministry of the Treasury charges fees to the establishments for the inspection services provided and transfers the appropriate funds to the Ministry of Health to fund the program. No inspection personnel receive any remuneration from the establishments they regulate.

The auditor conducted interviews with inspection officials in the Regions of Lombardia and Emilia-Romagna. The areas of responsibility of the various Regional offices are the same, but the organizational structure and the protocols for the periodic internal supervisory reviews may differ among the Regions:

Chain of Command	
Lombardia	Emilia-Romagna
There are 15 ASLs in Lombardia. Each Regional office works together with the government- owned and -operated IZS (laboratory) in the Region and pays for the analyses performed in the veterinary and inspection field. The main IZS is in Brescia; there are 7 additional secondary laboratories. Under the Regional General Director, there are 6 Offices, one of which is Veterinary Services (VS). VS is divided into two departments: Animal Health and	There are 9 Provinces in Emilia-Romagna and 11 ASLs (two each in the Provinces of Bologna and Forli-Cesena). The Regional office works together with the main government- owned and -operated IZS in in Brescia (in the Region of Lombardia); and pays for the analyses performed in the veterinary and inspection field out of funds provided by the national Ministry of Finance. In Emilia-Romagna, there are 8 additional secondary laboratories. Under

Safety of Foods of Animal Origin. Each ASL has a General Director, who coordinates 4 Departments, one of which is Veterinary Prevention. The Dept of Veterinary Prevention is divided into 3 services: Animal Health, Hygiene of Foods of Animal Origin, and the third deals with animal welfare, animal feeds, veterinary drugs, and animal by-products. There are two slaughter and 6 processing establishments in Lombardia certified for export to the United States.	the Regional General Director, there are 14 Offices, one of which is Veterinary Services (VS). VS is divided into two Departments, Animal Health and Safety of Foods of Animal Origin. Each ASL has a General Director, who coordinates 4 Departments, one of which is Public Health. The Dept of Public Health is divided into 4 services: Public Health and Hygiene, Food Safety and Nutrition, Prevention and Safety in the Workplace, and Veterinary Public Health. There are 67 processing establishments and one slaughter establishment in Emilia-Romagna certified for export to the United States.
Periodic Internal Supervisory Reviews	
Lombardia	Emilia-Romagna
The Lombardia Regional officials perform two kinds of audits: Each ASL is audited at least once per year (approximately 20 audits per year) and each US-eligible establishment is also audited at least once per year. For this calendar year, 20 audits are scheduled and 16 have been performed. An establishment audit generally takes one day (8-12 hours); an ASL audit generally takes 3-4 days and includes visits to several establishments. Some audits of establishments and ASLs are conducted by multiple officials from the Regional office, particularly when large establishments with complex operations are involved. When specific problems have been identified, other subject-matter experts are included in the inspection team. No such problems have occurred recently in meat establishments, but in March-April 2008 there was a Listeria problem in a milk-processing establishment; the Regional Director carried out a two-day in-depth review which included the Director of the Food Microbiology Laboratory in Brescia and his assistant, the responsible official from the ASL, the Official Veterinarian in the establishment, one colleague from the MOH, and one microbiologist from the National Reference Laboratory in Rome.	The Regional officials in Emilia-Romagna conduct two kinds of audits: A full system audit of each of the eleven ASLs is performed at least annually, and additional audits of specific sectors of activity are performed. As of the time of this current audit, three "sectorial" audits (with emphases on slaughter establishments, cold storage facilities, and trichina laboratories) had been conducted in 2009. In 2008, more than ten "sectorial" audits were performed; the sectors included the rapid-alert system, animal feeds, and trichina controls. The Emilia-Romagna Regional officials conduct audits of approximately 10% of the 69 US-eligible establishments per year. For this calendar year, three have been performed; 5 were conducted in 2008. An establishment audit generally takes one day (all audits included pre-operational sanitation verification. Audits of establishments and ASLs are typically conducted by multiple officials from the Regional office. When "sectorial" audits are conducted, other subject-matter experts are included in the inspection team. In 2008, during a "sectorial" audit of trichina laboratories, a microbiologist was included in the team. During an audit of Est. 476L, conducted by MOH and Regional officials in October 3, 2008, non-compliances regarding personal hygiene, maintenance of over-product equipment, control of inedible products, and cross-contamination were identified. A NOID was issued. The Regional officials conducted a follow-up audit 30 days after the establishment received written notification of the audit report; some of the corrective actions were not yet complete. The Regional officials recommended delistment of the establishment and the Ministry officials agreed and delisted it.

The auditor also conducted interviews with inspection officials in the ASL in Modena (in the Region of Emilia-Romagna. The ASL in Modena Province is one of 11 ASLs in the Region of Emilia-Romagna (there are two each in the Provinces of Bologna and Forli-Cesena). This Province is divided into three territories, each of which has a Director.

One slaughter establishment and one processing establishment in the Province of Modena are certified for export to the US. During the audit of Est. 791L, conducted by FSIS on 4/21/2008, a NOID was issued. The ASL supervisor conducted a follow-up review on 5/9/2008 and reported that the corrective actions were complete. A further follow-up review was conducted by the Director of Office IX of the Ministry of Health on May 23; the ASL supervisor and the Official Veterinarian in the establishment participated. This review confirmed the completeness of the corrective actions, and the NOID was lifted. The MOH conducted further reviews on October 5 and November 28; corrective actions remained effective.

One US-eligible establishment in Modena Province (Est. 946L) was delisted on 11/24/2008. The ASL supervisor, during a routine review on 9/24/08, reported condensation adulterating product, rust on rails, gaps under outside doors, inadequate cleaning of equipment, and accumulations of old equipment on outside grounds. He wrote non-compliance reports requiring corrective actions and requested another review by the Regional officials. This was performed on 11/18/2008. Corrective actions were reported to be effective. The Director of the Regional office recommended delistment to the General Director of the Office of Food Safety and Nutrition in the MOH, and the establishment was delisted on 11/24/08.

Examples of internal supervisory audit reports were provided. Approximately one-fourth of the audits of the slaughter establishment included pre-operational sanitation verification. When the supervisor performs pre-operational sanitation verification, he inspects the facilities before the establishment employee conducts the normal pre-operational inspection, and then observes the latter to see if he/she finds the same non-compliances that were observed previously. (During the July 14 audit of the slaughter establishment, the supervisor reported two non-compliances that the establishment inspector had missed.) The focus of the internal reviews also routinely included establishment compliance with HACCP, SSOP, and SPS requirements, and also the performance of the in-plant inspection officials. One deficiency noted was that the Official Veterinarian had not used the correct official form for evaluation of FSIS requirements, which contains English translations of the items on the checklist.

7.2.2 Ultimate Control and Supervision

The CCA has ultimate control over all establishments certified for export to the United States. MOH headquarters officials perform one-day supervisory audits of at least 10% of the US-eligible establishments each year; these reviews include reviews of the ASLs' supervision of the establishments. During the 2008 calendar year, MOH performed internal audits of 10 establishments and 7 ASLs. The MOH establishment audits cover HACCP programs, SSOPs, SPS, microbiological and residue sampling, and evaluation of the activities of the in-plant inspection staff. MOH officials also evaluate the Regional activities during the establishment reviews. The Regions are supervised for export activities by Office IX (Foodstuffs Export) of DGSAN. The Regions perform supervision of the ASLs with a frequency determined by the officials of each Region. The periodic internal reviews are performed by the ASL officials at a frequency

determined by the supervisor of each ASL according to the operations conducted in the establishment: Slaughter and/or cutting plants must be reviewed at least monthly, boning establishments are at least every 3 months, establishments producing bone-in dry-cured ham at least every 4 months, and all other establishments (slicing, cooking, etc.) at least every two months. Furthermore, during approximately half of the MOH supervisory internal audits, veterinarians from different Regions are invited and accompany the officials, for purposes of correlation and continuing education. The reports from the periodic internal supervisory reviews conducted by the ASL officials are provided to the Regional Office for evaluation.

The CCA has ultimate control over all government laboratories. Within the Italian Ministry of Health's Dept. of Veterinary Health, there are three Units. Unit II provides direct oversight of the microbiology laboratories; all microbiology laboratories employed for analysis of US-eligible products are government-owned and -operated. The technical branches of the Ministry of Health that deal with veterinary public health issues in the autonomous regions and provinces form the IZS; there are 10 IZS headquarters, 8 of which serve more than one autonomous region or province. Five of the IZS territories (whose headquarters are in Torino, Brescia, Padova, Roma, and Teramo) contain US-eligible establishments. All media used in the official microbiology laboratories are prepared in the IZS headquarters laboratory in each IZS territory and shipped to the other laboratories. Unit II conducts the audits of the official laboratories and also verifies compliance with technical requirements at least every 15 months (usually within each fiscal year). The audits cover FSIS' Microbiology Laboratory Guidebook methods for ready-to-eat product testing for *Listeria monocytogenes* and *Salmonella*. An independent organization (SINAL) performs accreditation of the Italian residue and microbiology laboratories. A single work-sheet model is used for analysis of US-eligible product in all official laboratories. There is a system in place through which specific technical instructions that describe FSIS-approved methods are provided to all microbiology and residue laboratories; their implementation is verified during the internal reviews.

Blank health certificate forms are provided on the MOH website. The field veterinarians access the form electronically and print it. When a form is filled out, it must be stamped with an official seal to be valid. Each health certificate bears a unique identification number that is assigned at the ASL level. There two kinds of seals: One is issued directly to each veterinarian (it contains the name and title of the person and the person carries it to each assignment and keeps it under security in the inspection office while at the establishment) and the other (the official seal of the General Health Directorate, Regional Office) is issued to each veterinary office and is kept under security at all times, when not in use. A Regional Note (in Lombardia) was provided to the field in May 2009 enumerating and clarifying procedures for the protocols for issuance of health certificates for each country to which meat products are exported.

7.2.3 Assignment of Competent, Qualified Inspectors

All official veterinarians must hold professional degrees from recognized schools of veterinary medicine and must attend an additional 3-year post-graduate university course ("Specialization School") that includes public health, inspection of foodstuffs, and infectious and food-borne diseases. MOH organizes supplementary courses for official veterinarians in US-eligible export establishments. Two such courses have been conducted in 2009—one in January in Parma conducted by an American consulting group covering HACCP, SSOPs, and SPS, and the other in San Daniele in April covering the collection of data in the electronic ICARUS system database (for *Listeria* and *Salmonella* testing and results).

Non-veterinary (auxiliary) local-level inspection personnel are employed in areas in which there are a large number of processing establishments, e.g., in Parma. They receive specific food-production courses and on-the-job training with official veterinarians; their education includes additional training in US requirements.

Veterinarians working at the headquarters and Regional levels are not allowed to work outside the Agency. Inspection officials assigned to the establishments are permitted to engage in outside employment, but only with the prior approval of the General Director of the ASL after he/she has determined that there is no possibility of a conflict of interest. One veterinarian, the Official Veterinarian (equivalent to the Inspector-In-Charge) in two establishments audited in the Region of Friuli, had a small-animal practice in a town some 20 miles from the establishments. She provided the official attestation from the General Director of the ASL granting her permission to engage in this outside employment.

7.2.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and the responsibility to enforce US and European Commission (EC) requirements. EC Regulations 852/2004, 853/2004, and 882/2004 define the Central Competent Authority of each Member State. Italy's Legislative Decree No. 193 (November 6, 2007), Article 2 describes the Competent Authorities at the various levels (the Ministry of Health, the 19 Regions, the two Autonomous Provinces of Trento and Bolzano, and the ASLs).

EC Regulation 882/2004 states that each Member State determines the fees to be paid for official inspection controls, and each Member State also decides what portion of the fees shall be reimbursed by the establishments for inspection services provided and what additional fees are to be levied for additional services, e.g., in export facilities. This is transposed into Italian law under the Gazzetta Ufficiale No. 289 (December 11, 2008), Legislative Decree No. 194 (November 19, 2008).

When non-compliance is identified, the official veterinarian has full authority to take enforcement actions ranging from production slowing/stoppage, product retention, rejection of equipment and facilities, up to and including suspension of the

establishment's operations, the issuance of a NOID, and (together with Regional officials) delistment. Documentation of these enforcement actions was provided: A NOID was issued to Establishment 476L on 10/14/2008 following the determination of non-compliance with US requirements during a routine monitoring (audit) activity. The Regional officials conducted a follow-up audit on November 14, 2008 and determined that the establishment had not taken effective corrective actions. The establishment was delisted one week later (on November 21).

7.2.5 Adequate Administrative and Technical Support

The supervisor of each ASL assigns inspection staff to the establishments. The responsibility for providing relief in case of planned or unplanned absence lies with the ASLs, since the latter assign the in-plant inspection personnel and provide direct technical support to the establishments. Relief is usually provided from a pool of inspection personnel assigned to other establishments; some establishments are large enough that a veterinarian not assigned to line inspection can cover an absence. For example, five veterinarians are assigned to the slaughter establishment in Emilia-Romagna; all of them are qualified to serve as Official Veterinarian in case of planned or unplanned absence. Several well-documented examples of both pre-scheduled and unplanned relief coverage were provided during the course of the country audit. In the ASL in Modena, there are two employees who are qualified to substitute for the inspection personnel assigned to the US-eligible processing establishment.

When the management officials of a new establishment are interested in becoming eligible to export to the United States, their first step is to express that interest to the Regional office. The Regional officials conduct an in-depth verification audit to ensure that the establishment is in compliance with all requirements. During these audits, the Regional officer also conducts refresher training for the inspection personnel in the establishment. Typically, multiple audits are necessary. (An example was provided for an establishment in the Lombardia Region whose management officials expressed interest in September 2008; four audits had been conducted as of the date of this interview, and for this establishment, further improvement was still required.) When the Region has determined that the establishment controls are in compliance, the Regional officials inform the headquarters officials in the MOH; the establishment then submits a formal application to the MOH through the Regional office. A final audit is carried out by officials from the MOH. If the audit is successful, the establishment is added to the eligibility list.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters and regional offices, and also in inspection offices in the audited establishments. These document reviews focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.

10. SANITATION CONTROLS

As stated earlier, FSIS auditors focus on five areas of risk to assess Italy's meat inspection system. The first of these risk areas that the FSIS auditor(s) 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, Italy's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature controls, work space, ventilation, ante-mortem facilities, and outside premises.

10.1 Sanitation Standard Operating Procedures

Each of the establishments audited was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The SSOPs in all of the 14 establishments audited were found to meet the basic FSIS regulatory requirements; two incidents of non-compliance with SSOP requirements were reported:

- In one processing establishment, two workers removing the bones from hams were observed to contact the edges of a container for inedible materials (bones) with their mesh gloves. The inspection officials immediately ordered that they clean and sanitize their mesh gloves and that the bone container be repositioned farther away from their work areas.

- In one processing establishment, several packages of meat wrapped in plastic, on two pallets, were observed in a storage freezer with small tears in the plastic so that the meat was exposed. The inspection officials ordered reinspection of all of the product and condemnation of those packages with torn coverings; the establishment officials condemned the entire two affected pallets of product.

10.2 Sanitation Performance Standards

Sanitation Performance Standards in all establishments were found to meet the basic FSIS regulatory requirements; one implementation non-compliance was reported:

- In one processing establishment, a large pepper grinder was observed with several areas of rust and flaking paint on its outer (non-product-contact) surface. The grinder was immediately rejected for further use by the inspection officials.

10.3 EC Directive 64/433

No non-compliance regarding EC Directive 64/433 was reported.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor(s) reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Italy's inspection system had adequate controls in place.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor(s) reviewed was Slaughter/ Processing Controls. The controls include the following areas: Ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also included the implementation of HACCP systems and implementation of generic *E. coli* testing programs in all of the establishments audited.

12.1 Humane Handling and Humane Slaughter

No non-compliance was reported.

12.2 HACCP Implementation

Each slaughter and processing establishment certified to export meat products to the United States is required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the regulatory requirements.

The HACCP programs in all 14 establishments were found to meet the basic FSIS regulatory requirements; however, some aspects of these requirements were not met in ten of these. The following non-compliances were reported:

- In four establishments, the record-review portion of the verification of the monitoring procedures was performed as required, but the times when they were performed were not recorded.

- In three establishments, pre-shipment document reviews were performed as required, but the actual times when the reviews were performed were not recorded.

- In two establishments, the verification of thermometer calibration was not documented by the verifiers with the dates and times performed and their signatures or initials (the thermometers were calibrated regularly as required).

- In one establishment, the monitoring documentation contained only one notation representing absence of feces/ingesta/milk for all 340 swine carcasses in one hour's production; however, any carcasses with contamination, and corrective actions taken, were documented individually.

- In one establishment, all of the verification procedures of the monitoring activities were performed as required, but the times when they were performed were not recorded.

- In one establishment, the description of the verification procedures in the written HACCP plan did not include direct observation of the monitoring activities (although the Quality Control manager was actually conducting and documenting some direct observation of the monitoring procedures).

As stated earlier, although HACCP non-compliances were reported in ten establishments, nine of these were attributable to minor record-keeping details, and one was an inadequate description a verification activity in the written HACCP plan (the activity was actually being performed and documented).

12.3 Testing for Generic *E. coli*

FSIS has made an equivalence determination for European Community Member States to test for *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli.*

Two of the 14 establishments audited were required to meet the regulatory requirements for the alternative testing program for *Enterobacteriaceae* and Total Viable Count and were evaluated according to the criteria set out in this program. This testing was conducted properly in both of the establishments in which it was required.

12.4 Testing for *Listeria monocytogenes*

Eight of the 14 establishments audited were producing ready-to-eat products that were required to meet the basic FSIS regulatory requirements for testing for *Listeria monocytogenes* and were evaluated according to the applicable regulations.

Testing for *Listeria monocytogenes* was conducted properly in all of the eight establishments in which it was required.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor(s) reviewed was Residue Controls. These 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.

Italy's residue testing program was evaluated at the establishment level. No non-conformance was reported. The National Residue Testing Plan for 2009 was on schedule.

13.1 EC Directive 96/22

No residue laboratories were audited. At the establishment level, the provisions of EC Directive 96/22 were effectively implemented.

13.2 EC Directive 96/23

No residue laboratories were audited. At the establishment level, the provisions of EC Directive 96/23 were effectively implemented.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor(s) reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements such as required inspection coverage, the testing programs for *Salmonella,* and species verification.

- Non-compliances that should have been identified in advance by inspection officials and corrected prior to this audit were reported in ten of the 14 establishments audited; in six of these establishments, they involved only minor record-keeping details.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily, whenever US-eligible products were being produced, in all of the 14 establishments audited.

14.2 Testing for *Salmonella* species

Italy has adopted the FSIS requirements for testing for *Salmonella* to meet the *Salmonella* Performance Standards, with the exception of two alternative procedures that have been determined by FSIS to be equivalent:

- Government laboratories use ISO 6579 and AOAC 967.25 to analyze samples for *Salmonella.*

- Italy uses five 75-gram samples for testing of Ready-To-Eat (RTE) product for *Salmonella*.

Two of the 14 establishments audited were required to meet the basic FSIS regulatory requirements and those of the equivalence determinations for *Salmonella* testing and were evaluated according to these requirements.

Testing of carcasses for *Salmonella* species was conducted properly in both of the establishments in which it was required.

14.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

14.4 Periodic Supervisory Reviews

In all of the establishments audited, supervisory reviews of certified establishments were being performed and documented as required.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. Also, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

A closing meeting was held on September 29 in Rome with the CCA. In this meeting, the auditor presented the primary findings.

The CCA understood and accepted the findings.

Gary D. Bolstad, DVM
Senior Program Auditor

January 4, 2010

15. ATTACHMENTS

- 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
Levoni S.p.A. Via Matteotti, 23 Castellucchio, Lombardia 0	09/15/2009	5L	Italy
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

Date: 09/15/2009 Est #: 5L (Levoni S.p.A. [P]) (Castellucchio, Italy)

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
Gary D. Bolstad, DVM	January 4, 2010

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agricola Tre Valli Soc. Coop. A.r.L. Via Venezia 228 San Daniele del Fruili, Friuli 0	09/09/2009	163L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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.	
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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 09/09/2009 Est #: 163L (Agricola Tre Valli Soc. Coop. A.r.L. [P]) (San Daniele del Fruili, Italy)

22/51. The times when the document-review portion of the verification procedures were performed were not recorded. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the past eight months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

39. Several openings where pipes passed through ceilings and walls were not completely sealed; none of these were above exposed-product or personnel-traffic areas. Some of these were identified for correction by the accompanying inspection service personnel; others were noted by the auditor. All were immediately scheduled for prompt sealing. [9 CFR §416.2(b)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	G D Bolstad DVM February 4, 2010

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Prosciuttificio San Francesco S.p.a. Via Grossardi 2 Medesano, Emilia Romagna 0	09/23/2009	167L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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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9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 09/23/2009 Est #: 167L (Prosciuttificio San Francesco S.p.a. [P]) (Medesano, Italy)

22/51. The verification of thermometer calibration was not documented by the verifier with the date and time performed and signature or initials. A review of documentation generated by the Official Veterinarian (IIC) during the previous 30 days and by the periodic internal supervisory reviewers during the previous 8 months indicated that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	G D Bolstad DVM February 4, 2010

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. Via Confine, 4 Cola di Lazise, Veneto 0	09/14/2009	169L	Italy
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [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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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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 09/14/2009 Est #: 169L (Leoncini S.R.L. [P]) (Cola di Lazise, Italy)

22/51. The times when the document-review portion of the verification procedures were performed were not recorded. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews during the past six months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	G D Bolstad DVM March 4, 2010

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 Baldo S.r.L. Viale Italia 21 Cantu, Lombardia 0	09/03/2009	348L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary Bolstad, DVM		[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	
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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 09/03/2009 Est #: 348L (Salumificio Baldo S.r.L. [P]) (Cantu, Italy)

22/51. The establishment was performing pre-shipment document reviews as required, but the documentation did not contain the actual times when the individual reviews were performed. Reviews of HACCP-program verification records by both the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews ofer the course of the previous 6 months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary Bolstad, DVM	February 4, 2010

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. S. Dorligo della Valle San Dorligo della Valle, Friuli	09/11/2009	478L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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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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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 09/11/2009 Est #: 478L (Principe di San Daniele S.p.A. [P/CS]) (San Dorligo della Valle, Italy)

10. Several packages of meat wrapped in plastic were observed in a storage freezer with tears in the plastic so that the meat was exposed. The inspection officials ordered reinspection of all of the product and condemnation of those packages with torn coverings; the establishment officials condemned the entire two affected pallets of product. [Regulatory reference(s): 9 CFR §416.13]

22/51. The times when the document-review portion of the verification procedures were performed were not recorded. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous six months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	GD Bolstad DVM February 4, 2010

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
Rovagnati S.p.A. Fermi 19 Biassono, Lombardia 0	09/02/2009	508L	Italy
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 09/02/2009 Est #: 508L (Rovagnati S.p.A. [P/CS]) (Biassono, Italy)

22/51. The establishment was performing pre-shipment document reviews as required, but the documentation did not contain the actual times when the individual reviews were performed. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and the regional supervisor during the periodic supervisory reviews over the course of the previous 90 days showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	GD Bolstad DVM February 4, 2010

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 Srl Vezzano 99 Silandro 39028	09/07/2009	621L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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.	
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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

10/51. While conducting operational sanitation inspection, a large pepper grinder was observed with several areas of rust and flaking paint on its outer (non-product-contact) surfaces. Reviews of pre-operational and operational sanitation records by both the in-plant inspection personnel and the regional supervisor during the periodic supervisory reviews showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. The grinder was immediately rejected for further use by the inspection officials. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 416.13, 416.17]

15/51. The description of the verification procedures in the written HACCP program did not include direct observation of the monitoring activities, although the Quality Control manager was actually performing and documenting some direct observation of the monitoring activities. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous six months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [9 CFR §327.2(a)(2)(i)(D), 417.2(c), 417.8]

16/51. The establishment was performing pre-shipment document reviews as required, but the documentation did not contain the actual times when the individual reviews were performed. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous six months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [9 CFR §327.2(a)(2)(i)(D), 417.2(c), 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
	D Bolska MV February 4, 2010

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Martelli F.lli S.p.A Via Cantone 22/24 Dosolo (Mantova), Lombardia 46030	09/21/2009	643MSL	Italy
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [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	
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	
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

Date: 09/21/2009 Est #: 643MSL (Martelli F.lli S.p.A [S/P/CS]) (Dosolo (Mantova), Italy)

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
Gary D. Bolstad, DVM	GD Bolstad DVM February 4, 2010

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. VIA DEL PONTE, 4 SAN GIMIGNANO (SI) 53037	08/28/2009	718L	ITALY
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. Delistment	
59.	

60. Observation of the Establishment

22/51. The times when the verification procedures for the monitoring activities were performed were not recorded. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous 90 days showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. (The review forms contained specific instructions for verifying the dates when verification procedures were performed and the signature or initials of the person(s) performing the verification.) [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR

Alam Khan

62. AUDITOR SIGNATURE AND DATE

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
A & B Prosciutti S.p.A. San Daniele del Friuli (UD) Localita Aonedis San Daniele del Friuli, Friuli 0	09/10/2009	720L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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.	X
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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 09/10/2009 Est #: 720L (A & B Prosciutti S.p.A. [P]) (San Daniele del Friuli, Italy)

22/51. The verification of thermometer calibration was not documented by the verifier with the date and time performed and signature or initials. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous eight months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

22/51. The times when the document-review portion of the verification procedures were performed were not recorded. Reviews of HACCP-program verification records by the in-plant inspection personnel during the previous 30 days and by the regional supervisor during the periodic supervisory reviews over the course of the previous eight months showed that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	G D Bolstad MV February 4, 2010

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 Via per Gualtalla 21/A Carpi, Emilia-Romagna	09/24/2009	791MS	Italy
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [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.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Date: 09/24/2009 Est #: 791MS (Italcarni Societa Cooperativa [S/P/CS]) (Carpi, Italy)

16/51. The monitoring documentation contained one notation representing absence of feces/ingesta/milk for all units in one hour's production. A review of documentation generated by the Official Veterinarian (IIC) during the previous 30 days and by the periodic internal supervisory reviewers over the course of the previous 90 days indicated that this non-compliance had not been identified by the inspection officials prior to the date of this current audit. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.2(c), 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	G D Bolstad DVM February 4, 2010

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
Industrie Salumi Faenza Isaf S.r.L. Via Galvani 26 Faenza, Emiglia-Romagna 0	09/18/2009	972L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

Date: 09/18/2009 Est #: 972L (Industrie Salumi Faenza Isaf S.r.L. [PJ] (Faenza, Italy)

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
Gary D. Bolstad, DVM	February 4, 2010

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
Ditta Prosciutti Rosa S.p.A. Via Poirino 21 10046 Isolabella Torino, Piemonte 0	08/31/2009	1249L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[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.	
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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	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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 08/31/2009 Est #: 1249L (Ditta Prosciutti Rosa S.p.A. [P/CS]) (Torino, Italy)

10. Two workers removing the bones from hams were observed to contact the edges of a container for inedible materials (bones) with their mesh gloves. The inspection officials immediately ordered (1) that they clean and sanitize their mesh gloves and (2) repositioning of the bone container farther away from their work areas. [Regulatory reference(s): 9 CFR §416.13]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	February 4, 2010

Ministero della Salute

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

James Adams, DVM, Director
USDA, FSIS, OIA, IAS
1400 Independence Ave. SW, Room 2139-South
Washington, DC 20210
Fax 202-720-0676

e p. c. Andreas Keller, Ph.D., Director
USDA, FSIS, OIA, IES
Room 3805-S
1400 Independence Ave., SW
Washington, DC 20250
Fax 202-690-4040

Ambasciata degli
Stati Uniti d'America
Roma
Fax n° 06-47887008

Subject: Draft Final Report (FSIS Audit Sept. 2009)

Dear,
thanks for your letter of 12-04-09.
We received the Draft related to the last FSIS mission to Italy.
We understood and accept the findings and we agree on your draft report.
Just one minor edit. At page 12 line 5th should be: the Director of Office IX of Ministry of Health and not the Director of the Ministry.
Best regards,

Silvio Borrello
General Director