



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Radu C. Roatis
President, Veterinary and Food Safety National Authority
1B Negustori Street
Bucharest, Romania 023951

MAR 18 2009

Dear Dr. Roatis:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Romania's meat inspection system August 25 through September 10, 2008. Comments from the government of Romania have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

Manzoor H. Chaudry, DVM

Manzoor Chaudry, DVM
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

MAR 18 2009

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

AUGUST 25 THROUGH SEPTEMBER 10, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CFR	Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
HVPHD	Hygiene and Veterinary Public Health Directorate
NSVFSA	National Sanitary Veterinary and Food Safety Authority
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Romania from August 25 through September 10, 2008. This was a routine audit. Romania is eligible to export processed pork meat to the United States. At the time of the audit, three establishments were eligible to export to the United States. During calendar year 2007, and through August of 2008, Romania did not export processed pork meat to the United States. Activities of the current audit appear in the table below.

The findings of the previous audit conducted during July 11 through August 2, 2005, resulted in no restrictions of any Romanian establishment's ability to export processed pork meat to the United States.

1.2 Comparison of the Current Audit and the Previous Audit

		CURRENT AUDIT DATES: August 25 through September 10, 2008	PREVIOUS AUDIT DATES: July 11 through August 2, 2005
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	3
	Establishment Level	3	4
Laboratories Audited			
	Microbiology	1	1
	Residue	0	1
Establishments Audited			
	Slaughter/processing	1	2
	Processing only	2	2
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	1
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	8	5
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	4	9
	Residue Controls	0	0
	Microbiology Controls	2	0
	Inspection/Enforcement Controls	0	3
	Special Emphasis (HH, O157:H7)	0	0

1.3 Summary Comments for the Current Audit

The results of this audit reflected increased findings in the risk area of Sanitation Controls.

2. INTRODUCTION

The audit took place in Romania from August 25 through September 10, 2008.

An opening meeting was held on August 25, 2008, in Bucharest with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Romania's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the National Sanitary Veterinary and Food Safety Authority (NSVFSA), Hygiene and Veterinary Public Health Department (HVPHD), and representatives from the regional and local inspection offices.

3. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one regional inspection office, three local government offices at the establishment level, one microbiological laboratory performing analytical testing on U.S.-destined product, one slaughter/processing establishment, and two meat processing establishments.

4. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection Headquarters, one regional office, and three local government offices at the establishment level. The third part involved on-site visits to three establishments: one slaughter/processing establishment, and two processing establishments. The fourth part involved a visit to one government microbiology laboratory, "Sanitary Veterinary and Food Safety Regional Laboratory" which was testing for the presence of *Salmonella*. Program effectiveness determinations of Romania's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *Escherichia coli* (*E. coli*), (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Romania's inspection system was assessed by evaluating these five risk areas.

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

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, SPS, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Romania under provisions of the Sanitary/Phytosanitary Agreement.

The following measures have been recognized by FSIS as equivalent:

- Samples for testing for generic *E.coli* are analyzed in a government laboratory.
- The depth of excision for samples for testing *Salmonella* species is different.
- Samples for testing for *Salmonella* species are composited in the laboratory.
- Romania uses the ISO 6579 method for testing for *Salmonella* species.
- The Government of Romania has requested an exemption for species testing. This is being reviewed by FSIS.
- FSIS has determined that the use of *Enterobacteriaceae* and Total Viable Count in lieu of testing for generic *E. coli* is acceptable for all European Union (EU) exporting countries. However, the slaughter establishment certified to export product of the United States had decided to test for generic *E. coli*.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR, Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

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

- Council Directive 64/433/EEC of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"

- Council Directive 96/22/EC of 29 April 1996, entitled “Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of β -agonists”

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS website at the following address:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following findings were reported from the May/June 2004 FSIS audit:

- HACCP monitoring records did not include initials for each entry.
- Verification records did not identify the type of verification procedures performed by the responsible establishment employee.
- Carcass selection for generic *E.coli* testing was not random.

All deficiencies noted during the May/June 2004 FSIS audit had been addressed and corrected.

The following findings were reported from the July/August 2005 FSIS audit:

- The establishment did not follow its verification frequency for calibration of process-monitoring equipment in accordance to its HACCP plan.
- The HACCP verification records did not document the results of ongoing verification.
- The HACCP monitoring and verification records did not document the time the specific event occurred.
- In one establishment, direct product contamination due to dripping condensation onto exposed swine carcasses and equipment containing edible products was observed.
- Two establishments had SSOP record keeping deficiencies.
- Rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel containers, which may prevent the adequate removal of product residue and could become a source of product contamination.

All deficiencies noted during the July/August 2005 FSIS audit had been addressed and corrected.

7. MAIN FINDINGS

7.1 Government Oversight

The National Sanitary Veterinary and Food Safety Authority (NSVFSA) is an authority under the coordination of the Minister of Agriculture, Forestry and Rural Development and under direct supervision of the President of the NSVFSA.

The NSVFSA has four General Directorates as follows:

- 1) General Sanitary Veterinary Directorate.

- 2) General Food Safety Directorate.
- 3) General Directorate for Inspection, Control, and Coordination of Border Inspection Post.
- 4) General Directorate for Budget, Financing, Legal Affairs, and Human Resources.

Hygiene and Veterinary Public Health Directorate (HVPHD) is now under the supervision of one of the two Vice-President Sub-Secretaries of State, since January 2006. The HVPHD is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced.

7.1.1 CCA Control Systems

The HVPHD regulatory oversight of its meat inspection system consists of three levels: central, district, and local. HVPHD provides direct oversight of 42 district veterinary offices. Each district veterinary office provides supervision over establishment offices for the control of products of animal origin. There is a different state veterinary laboratory in each district.

Currently, Romania has three establishments that are certified to export to the United States. The government oversight for these establishments is being managed by three district offices in Bihor, Teleorman, and Suceava.

FSIS requirements and inspection documents are distributed from headquarters to districts via an intranet system and by fax. This system has been developed to ensure that the information effectively reaches its destination, and all records are properly maintained.

The HVPHD employs approximately 1215 personnel to carry out the responsibilities of its domestic and meat export inspection programs, including related enforcement activities. All HVPHD inspection personnel assigned to establishments certified to export meat to the United States are government employees receiving no remunerations from either industry groups or establishment personnel.

7.1.2 Ultimate Control and Supervision

The HVPHD has the legal authority to supervise and enforce Romania's meat inspection activities and FSIS regulatory requirements through its linear government oversight, i.e., headquarters to districts to local and/or establishment offices.

The in-plant inspection personnel are supervised by the veterinarian-in-charge (VIC) who has the authority to cease the establishment's production operation any time the wholesomeness and safety of the product are jeopardized. The VIC reports and consults all decisions regarding enforcement activities with his/her immediate supervisor. The decision as to whether a certified establishment is failing to meet FSIS inspection requirements, and the recommendation that it should be delisted, is a combined effort of the applicable district director and headquarter officials.

Periodic supervisory reviews of all certified establishments were being performed at least quarterly by each district official. The CCA has a delegated person with the

responsibility to ensure that certified establishments are meeting FSIS inspection requirements.

The HVPHD employees cannot perform any private or establishment-paid tasks.

7.1.3 Assignment of Competent, Qualified Inspectors

All inspection personnel possess the required educational degree necessary to meet minimum qualifications set by HVPHD. They have passed a written exam and oral interview as well as participation in the introductory training courses and on-the-job training under the supervision of the experienced veterinarians. For the three certified establishments audited, HVPHD has placed a sufficient number of official inspection personnel to carry out FSIS and Romania's meat inspection requirements. However, Romania's inspection system needs to continue providing training to inspection personnel regarding U.S. inspection requirements, including training in government enforcement of HACCP and SSOP requirements.

All in-plant inspection personnel are rated annually by their immediate supervisor. These performance ratings are sent to a special commission in each district for review and evaluation.

7.1.4 Authority and Responsibility to Enforce the Laws

The HVPHD has the authority to carry out Romania's meat inspection program, including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. HVPHD not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

7.1.5 Adequate Administrative and Technical Support

The HVPHD has adequate administrative and technical support to operate Romania's meat inspection system and has the resources and the ability to support a third-party audit.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters, three district offices, and three in-plant inspection offices at the audited establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.

- Sanitation, slaughter and processing inspection procedures and standards.
- Enforcement records, including consumer complaints, recalls, and control of noncompliant product.
- Export product inspection and control, including export certificates. Romania has not been exporting any meat products to the United States for the past several years.

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

7.2.1 Audit of Regional and Local Inspection Sites

The FSIS auditor reviewed Romania's meat inspection records and held interviews with the HVPHD inspection officials at the district office as below:

- Teleorman District Office in Alexandria.

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

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of three establishments. There was one slaughter/processing establishment and two processing establishments. No establishment was delisted or received a Notice of Intent to Delist (NOID) by Romania's inspection officials.

Specific deficiencies are listed in the attached individual establishment reports.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

While an actual residue laboratory visit was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, Regional, and local inspection offices.

During these interviews, emphasis was placed on ensuring that the application of procedures and standards are equivalent to U.S. requirements. Assessment of the residue laboratory focused on timely analysis, analytical methodologies, and recording and reporting of results.

No concerns arose as a result of these interviews.

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

The following laboratory was audited:

“Sanitary Veterinary and Food Safety Regional Laboratory” is a government microbiology laboratory, located in Alexandria, Romania.

The following deficiencies were reported:

- Calibration for one of the two incubators used for *Salmonella* testing was not being conducted.
- The weighing scale used in the sample receiving room had not been calibrated since December 5, 2006.

10. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess Romania’s meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, Romania’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, Romania’s inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

Specific deficiencies are listed in the attached individual establishment reports.

10.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met according to the criteria employed in the U.S. domestic inspection program. In all of the three establishments audited, there was inadequate implementation of SSOP requirements.

The following deficiencies were reported:

- In all three establishments audited, documentation of corrective actions taken for SSOP deficiencies in the official inspection records did not include preventive measures.
- In one establishment, documentation of corrective actions taken for SSOP deficiencies in the establishment records did not include preventive measures.
- In one establishment, an employee in the meat cutting room picked up a piece of meat from the floor and put it in the edible product container, and subsequently handled meat in another edible container without removing or replacing his gloves or washing his hands.
- Documentation of corrective actions taken for SSOP deficiencies in the official inspection records did not include preventive measures.

10.2 SPS

The enforcement of all aspects of FSIS Sanitation Performance Standards (SPS) requirements was not implemented by government inspectors in the slaughter/processing establishment audited.

The following deficiencies were reported:

- The door in the finished-product loadout area had a gap of approximately three (3) inches on both sides of the platform, which could allow pests to enter the facility.
- During pre-operational sanitation inspection in the product drying room, it was observed that a metal piece that had been welded to a metal tank used to marinate raw product precluded thorough cleaning and inspection of the equipment.
- Heavily beaded condensate was observed on an overhead structure in a room where plastic tubs used for ready-to-eat products were stored.
- Buildups of product residues were observed on metal stands and product hanging rods to be used in the smoke house.

10.3 EC Directive 64/433

In all three establishments audited, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies are listed in the attached establishment report.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, 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 Romania'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 reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments, and implementation of a generic *E. coli* testing program in slaughter establishments.

12.1 Humane Handling and Slaughter

No deficiencies were reported.

12.2 HACCP Implementation.

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

The HACCP programs were reviewed during the on-site audits of the three establishments. Two of three establishments audited had not adequately implemented the HACCP requirements.

The following deficiencies were reported:

- Verification procedures for controlling fecal material, ingesta, and milk on carcasses on the slaughter floor were not being conducted by inspection officials.
- The documentation of verification procedures did not contain adequate information to determine which of the required elements of verification had been conducted.

12.3 Testing for Generic *E. coli*

Romania has adopted the FSIS requirements for generic *E. coli* testing with the exception of the following equivalent measure:

- Samples are being analyzed in a government laboratory.

One of the three establishments audited was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and was evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for generic *E. coli* was properly conducted in the slaughter establishment.

12.4 Testing for *Listeria monocytogenes*

All of the three establishments audited were producing ready-to-eat products for export to the United States. Two establishments were producing ready-to-eat products which were post-lethality exposed. One establishment was a canning facility which produced thermally processed/commercially sterile products.

The following deficiencies were reported:

- One establishment had not validated the log reduction achieved by the post-lethality treatment and antimicrobial agent in their process for *Listeria monocytogenes*.
- One establishment had not documented in its HACCP plan, in its SSOPs, or in its other prerequisite programs, the effectiveness of the antimicrobial agent or the process it employed in suppressing or limiting the growth of *Listeria monocytogenes*.

12.5 EC Directive 64/433

The provisions of EC Directive 64/433 were not effectively implemented in all three establishments audited. Specific deficiencies are noted in the attached establishment reports.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Romania's National Residue Control Program for 2008 was being followed and was on schedule.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in the certified establishments audited.

14.2 Testing for *Salmonella*

Romania has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

- The depth of excision is different.
- Samples are composited in the laboratory.
- The laboratory uses the ISO 6579 method to analyze for *Salmonella* species.

One of the three establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for *Salmonella* was properly conducted in the establishment audited.

14.3 Species Verification

Species verification was being conducted in those establishments in which it was required. Romania has requested exemption from the species verification requirement; the request is under consideration by FSIS's Office of International Affairs.

14.4 Periodic Supervisory Reviews

Periodic 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.

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

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

15. CLOSING MEETING

A closing meeting was held on September 10, 2008, in Bucharest with the CCA. At this meeting, the preliminary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Farooq Ahmad, DVM
Senior Program Auditor

p. Manzoor H. Chaudry, DVM

16. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report (when it becomes available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Principle Company S.A. Str. Ghestului, Nr. 10 Salonta 415500	2. AUDIT DATE 9/2/2008	3. ESTABLISHMENT NO. A-12	4. NAME OF COUNTRY Romania
	5. NAME OF AUDITOR(S) Farooq Ahmad, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 9/2/08 Est. #: A-12 (S.C. Principle Company S.A.) [P] (Salonta, Romania)

12 An employee in the meat cutting room picked up a piece of meat from the floor and put it in the edible product container and subsequently handled meat in another edible container without removing or replacing his gloves or washing his hands. The inspection officials took immediate corrective actions. [Regulatory references: 9 CFR §416.13 and EC Directive 64/433 Annex 1 Chapter 111]

12/13/51 Documentation of corrective actions taken for SSOP deficiencies in the official inspection records did not include preventive measures. The inspection officials gave assurances that prompt corrective actions would be taken. [9 CFR §416.15, §416.16 and §416.17]

19/22/51 The documentation of verification procedures did not contain adequate information to determine which of the required elements of verification had been conducted. The inspection officials gave assurances that prompt corrective actions would be taken. [9 CFR §417.4, 417.5, and §417.8]

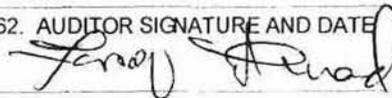
45 During pre-operational sanitation inspection in the product drying room, it was observed that a metal piece that had been welded to a metal tank used to marinate raw product precluded thorough cleaning and inspection of the equipment. The inspection officials took immediate corrective action: The tank was removed from the room. [9 CFR §416.3(a) and (b), and EC Directive 64/433, Chapter III(c)]

58/51 The establishment had not validated the log reduction achieved by the post-lethality treatment and antimicrobial agent in their process for *Listeria monocytogenes*. [9 CFR 417.4]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



9/16/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION FACOS Humorului Nr. 100 Scheia, Suceava 720330	2. AUDIT DATE 9/4/2008	3. ESTABLISHMENT NO. A-13	4. NAME OF COUNTRY Romania
	5. NAME OF AUDITOR(S) Farooq Ahmad, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 9/4/08 Est. #: A-13 (FACOS) [P] (Suceava, Romania)

12/13/51 Documentation of corrective actions taken for SSOP deficiencies in the establishment and official inspection records did not include preventive measures. The inspection officials gave assurances that prompt corrective actions would be taken. [Regulatory references: 9 CFR §416.15, §416.16 and §416.17]

41/56 Heavily beaded condensate was observed on an overhead structure in a room where plastic tubs were stored to be used for ready-to-eat products. The inspection officials ordered immediate corrective actions. [9 CFR §416.2(d), and EC Directive 64/433, ANNEX 1, CHAPTER 1(n)]

45/46/51 Buildups of product residues were observed on metal stands and product hanging rods to be used in the smoke house. The inspection officials ordered immediate corrective actions. [9 CFR §416.3(a), §416.4(a) and EC Directive 64/433, ANNEX 1, CHAPTER 111]

58/51 The establishment had not documented in its HACCP plan, in its Sanitation SOPs, or in its other prerequisite programs the effectiveness of the antimicrobial agent or process it employed in suppressing or limiting the growth of *Listeria monocytogenes*. [9 CFR §430.4(b)(1)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 9/16/2008

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Cicalex S.A. Str. Abatorului nr. 1- Alexandria	2. AUDIT DATE 8/27/2008	3. ESTABLISHMENT NO. 60	4. NAME OF COUNTRY Romania
5. NAME OF AUDITOR(S) Farooq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 8/27/08 Est. #: 60 (S.C. Cicalex S.A.) [S/P] (Alexandria, Romania)

12/13/51 Documentation of corrective actions taken for SSOP deficiencies in the official inspection records did not include preventive measures. The inspection officials gave assurances that prompt corrective actions would be taken. [Regulatory references: 9 CFR §416.15, §416.16 and §416.17]

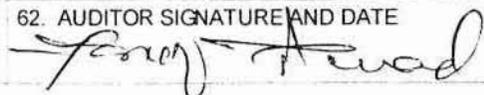
22/51 Verification procedures for controlling fecal material, ingesta, and milk on carcasses on the slaughter floor were not being conducted by inspection officials. The inspection officials gave assurances that prompt corrective actions would be taken. [9 CFR §417.8]

38/51 The door in the finished-product loadout area had a gap of approximately three inches on both sides of the platform, which could allow pests to enter the facility. The inspection officials gave assurances that prompt corrective actions would be taken. [9CFR §416.2(3) and EC Directive 64/433 Annex 1 Chapter 111 3(b)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 9/16/2008

ROMANIA



**AUTORITATEA NATIONALA SANITARA VETERINARA
SI PENTRU SIGURANTA ALIMENTELOR
CABINET PRESEDINTE – SECRETAR DE STAT**

Bucuresti Str. Neaustori nr. 1B sect 2 cod postal 023951 tel: 3157875 fax: 3124967 e-mail: office@ansv.ro

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
Mr. Donald SMART, Director, IAS, OIA
Fax: 202 720 0676**

**Ref: Draft final report – Audit covering Romanian meat inspection system,
from August 25 through September 10, 2008**

Regarding the Draft report on the audit of Romanian meat inspection system, from August 25 through September 10, 2008, performed by „Food Safety and Inspection Service” - United States Department of Agriculture experts, we communicate you that the National Sanitary Veterinary and Food Safety Authority has analyzed the recommendations given by the veterinary expert during the audit and those included in the draft report, and disposed to the County Sanitary Veterinary and Food Safety Directorates to apply corresponding measures.

National Sanitary Veterinary and Food Safety Authority has also transmitted the recommendations to the county veterinary services which are responsible for the official surveillance of the establishments, in order to apply proper measures to fix the deficiencies.

National Sanitary Veterinary and Food Safety Authority take this opportunity to express its highest consideration to the United States Department of Agriculture.

Sincerely,

PRESIDENT – SECRETARY OF STATE,

Marian ZLOTEA