



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

NOV 8 2004

Dr. Ion Sorin Mitrea  
Director General  
National Sanitary Veterinary Agency  
Ministry of Agriculture and Food  
Carol I Boulevard, No. 24  
Bucharest, Romania

Dear Dr. Mitrea:

The Food Safety and Inspection Service completed an on-site audit of Romania's meat inspection system. The audit was conducted from May 19 through June 9, 2004. The comments from Romania have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

Sally White, Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

Brian Goggin, Agricultural Attaché, US Embassy, Sofia

Cristina Cionga, Agricultural Specialist, US Embassy, Bucharest

RazVan Dumitrescu, Second Secretary Economic, Embassy of Romania

James Dever, FAS Area Director

Amy Winton, State Department

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Andreas Keller, IES, OIA, FSIS

Country File

**FINAL**

OCT 27 2004

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

**MAY 19 THROUGH JUNE 9, 2004**

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority, Hygiene and Public Health Department
FSIS	Food Safety and Inspection Service
HPHD	Hygiene and Public Health Directorate
NSVA	National Sanitary Veterinary Agency
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
VFSA	Veterinary and Food Safety Agency

## 1. INTRODUCTION

The audit took place in Romania from May 19 through June 9, 2004.

An opening meeting was held on May 19, 2004, 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 representative from the CCA, the Veterinary and Food Safety Agency, Hygiene and Public Health Department, and representatives from the regional and local inspection offices.

## 2. 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, three regional inspection offices, three establishment levels inspection, one reference laboratory performing analytical testing on United States-destined product, one slaughter establishment, and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Bucharest
	Regional	3	Bihor, Bacau, and Teleorman
	Local	3	Establishment level
Laboratories		1	
Meat Slaughter Establishments		1	
Meat Processing Establishments		2	

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to three establishments: one slaughter establishment and two processing establishments. The fourth part involved a visit to one government laboratory. The Hygiene and Veterinary Public Health Institute was conducting analyses of field samples for Romania's national residue control program as well as testing for the presence of generic *Escherichia coli* (*E. coli*) and *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 *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 the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that Romania's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Romania. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for Romania under provisions of the Sanitary/Phytosanitary Agreement. The following equivalent 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.
- Species testing – The Government of Romania has requested exemption. This is being reviewed by FSIS.
- *Listeria monocytogenes* testing – The Government of Romania has a surveillance program for ready-to-eat products for *Listeria monocytogenes* testing (one sample per month), but it is mandatory (every lot) if the product is exported.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

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

## 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:  
[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Foreign\\_Audit\\_Reports/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp)

In the audit of October 31 through November 14, 2001, the following findings were observed:

- Intended use of finished products was not mentioned in the plan.
- There was no documentation of pre-shipment review.

In the audit of December 4 through December 17, 2002, the following findings were observed:

- There was no differentiation between pre-operation and operation sanitation in the written Sanitation Standards Operating Procedures (SSOP).
- Cattle carcasses were contacting an electric box that was covered with peeling paint and product residues.
- Meat was dropped on the floor and was picked up by an employee and placed into a container with other edible meat. No attempt was made to recondition or re-inspect the contaminated product.
- Preventive measures were not recorded.
- There were no decision making documents to support the verification activities and their frequency.
- The written Hazard Analysis and Critical Control Point (HACCP) did not address corrective action.
- Aseptic techniques were not being followed during the collection of generic *E.coli* samples.
- The hazard analysis did not address chemical, physical, or biological hazards at each step in the flow diagram.
- The frequency of monitoring activities was not described for two critical control points.
- There were no decision making documents to support the monitoring activities.
- Records were not maintained at the time the event occurs.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

There has been a change in the organizational structure of the Romanian Veterinary Services since the last FSIS audit of Romania's meat inspection system in December 2002. The National Sanitary Veterinary Agency (NSVA), an agency under the Ministry of Agriculture and Food, has been renamed to Veterinary and Food Safety Agency (VFSA) and under direct supervision of the Secretary of State since January 2004.



The VFSA has four General Directorates as follow:

- 1) General Veterinary Directorate
- 2) General Food Safety Directorate
- 3) General Directorate for Inspection, Control, and Coordination of Veterinary Institutes
- 4) General Directorate for Economical, Administrative, Juridical, and International Relations

The General Veterinary Directorate is divided into Animal Health Directorate and Hygiene and Public Health Directorate (HPHD). The HPHD is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced.

#### 6.1.2. CCA Control Systems

The HPHD regulatory oversight of its meat inspection system consists of three levels: central, district, and local. HPHD provides direct oversight of 42 District Veterinary Offices. Each district veterinary office provides supervision over individual local or establishment offices for the control of products of animal origin. There is an afferent state veterinary laboratory in each district.

With regard to the three establishments currently certified to export to the United States, government oversight is being managed by three districts (Bihor, Bacau, and Teleorman).

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

The HPHD employs approximately 1230 personnel to carry out the responsibility of its domestic and export meat inspection programs including related enforcement activities. All HPHD 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.

#### 6.1.2 Ultimate Control and Supervision

The HPHD 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. 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.

Supervisory reviews of all certified establishments were being performed at least once a month by each district officials. CCA has a delegated person with the responsibility to ensure certified establishments are meeting FSIS inspection requirements. He participates in reviews of certified establishments four times a year.

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

### 6.1.3 Assignment of Competent, Qualified Inspectors

All inspection personnel possess the required educational degree necessary to meet minimum qualifications set by HPHD. 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. Continual training is provided for all inspection personnel as needed. The HPHD personnel in the headquarters, districts, and local offices as well as inspection personnel assigned to certified establishments received two training courses regarding PR/HACCP from a private contractor in May 2003 and April 2004. The district offices maintain individual training records of inspection personnel. Based on these records, all veterinarians assigned to the U.S. approved establishments are PR/HACCP trained. For the three certified establishments, HPHD has placed a sufficient number of official inspection personnel to adequately carry out the FSIS inspection 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.

### 6.1.4 Authority and Responsibility to Enforce the Laws

The HPHD 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. HPHD 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.

### 6.1.5 Adequate Administrative and Technical Support

It appeared that HPHD 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.

## 6.2 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.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

### 6.3.1 Audit of Regional and Local Inspection Sites

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

- Bihor District Office in Oradea, interviewed the Director and his associates
- Bacau District Office in Bacau, interviewed the Director and his associates
- Teleorman District Office in Alexandria, interviewed the Director and his associates

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

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of three establishments. One was slaughter establishment and two were processing establishments. None of the establishments were delisted by Romania. None of the establishments received a notice of intent to delist.

Specific deficiencies are noted in the attached individual establishment review forms.

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results,

and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratory was reviewed:

The Romanian Hygiene and Veterinary Public Health Institute, government reference laboratory at Bucharest, was audited. Both the residue department and the microbiological section of the lab were reviewed.

No deficiencies were noted.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses 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.

### 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in the three establishments were found to meet the basic FSIS regulatory requirements, with no deficiencies.

### 9.2 Sanitation

No deficiencies were noted.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, 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. No deficiencies were noted.

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

## 11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS 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.

### 11.1 Humane Handling and Slaughter

No deficiencies were noted.

### 11.2 HACCP Implementation.

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

The HACCP programs were reviewed during the on-site audits of the three establishments. Two establishments had not adequately implemented the HACCP requirements. The specific deficiencies were as follows:

- HACCP monitoring records did not include initials for each entry.
- Verification records did not identify the type of verification procedures (direct observation of monitor, review of the records, or calibration of process-monitoring instruments) performed by the responsible establishment employee.

### 11.3 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 United States' domestic inspection program.

Testing for generic *E. coli* was not properly conducted in one slaughter establishment. The carcass selection method for generic *E. coli* was not random in this establishment.

#### 11.4 Testing for *Listeria monocytogenes*

All of the three establishments audited were producing ready-to-eat products for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur, and all three establishments were routinely testing for this pathogen.

### 12. RESIDUE CONTROLS

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

The Hygiene and Veterinary Public Health Institute, Government Reference Laboratory in Bucharest was audited.

No deficiencies were noted.

Romania's National Residue Testing Plan for 2004 was being followed and was on schedule.

### 13. ENFORCEMENT CONTROLS

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

#### 13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

#### 13.2 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 United States' domestic inspection program.

Testing for *Salmonella* was properly conducted in this establishment.

### 13.3 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.

### 13.4 Monthly Reviews

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

### 13.5 Inspection System Controls

The CCA had controls in place for 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.

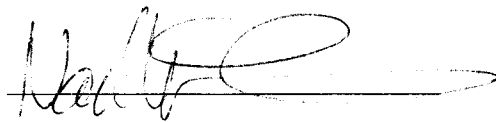
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

## 14. CLOSING MEETING

A closing meeting was held on June 9, 2004 in Bucharest with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Nader Memarian  
International Audit Staff Officer



## 15. ATTACHMENTS

Individual Foreign Establishment Audit Forms  
Individual Foreign Laboratory Reports  
Foreign Country Response to Draft Final Audit Report



FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY: Veterinary and Food Safety Agency  
 CITY & COUNTRY: Bucharest, Romania  
 ADDRESS OF LABORATORY: 6 Campul Mosilor Street, Sector 2, 78341-Bucharest

NAME OF REVIEWER: Dr. Nader Memarian  
 NAME OF FOREIGN OFFICIAL: Dr. Constantin Vasilescu, Director, Dr. Mihaela Dumitrache, Deputy Director, and Dr. Georgeta Briciu, Counsellor

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

Signature of reviewer: *Nader Memarian*

Date: 06-14-04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 05/24/04	NAME OF FOREIGN LABORATORY Hygiene and Veterinary, Public Health Institute
FOREIGN GOV'T AGENCY Veterinary and Food Safety Agency	CITY & COUNTRY Bucharest, Romania	ADDRESS OF LABORATORY 5 Campul Mosilor Street, Sector 2, 73341-Bucharest	
NAME OF REVIEWER Dr. Nader Memarian	NAME OF FOREIGN OFFICIAL Dr. Constantin Vasilescu, Director, Dr. Mihaela Dumitrache, Deputy Director, and Dr. Georgeta Briciu, Counsellor		
RESIDUE	ITEM NO.	COMMENTS	

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Cicalex S.A. Str. Abatorului nr. 1- Alexandria	2. AUDIT DATE 06/04/04	3. ESTABLISHMENT NO. 60	4. NAME OF COUNTRY Romania
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.			36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			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.			<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>			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	
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	
27. Written Procedures		X	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis			56. European Community Directives	O
29. Records			57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

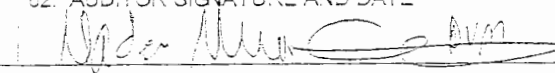
Country : Romania  
Date of Audit : 06/04/2004  
Establishment # 60  
Slaughter/Processing

27/51 The carcass selection method for generic *E. coli* testing was not random {9 CFR part 310.25(a)(2)(i)}.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE



06-14-04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SC Principal Construct SRL Str. Ghestului nr. 10 Salonta-Bihor, Romania	2. AUDIT DATE 05/26/2004	3. ESTABLISHMENT NO. A-12	4. NAME OF COUNTRY Romania
5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment:

Country : Romania  
Date of Audit : 05/26/2004  
Establishment A-12  
Processing

22/51 Verification records did not identify the type of verification procedures (direct observation of monitor, review of the records, or calibration of process-monitoring instruments) performed by the responsible establishment employee {9 CFR part 417.5 (a) (3)}.

61. NAME OF AUDITOR  
Nader Memarian DVM

62. AUDITOR SIGNATURE AND DATE

*Nader Memarian* DVM

06-14-04

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agricola International 5, Abatorului Street 5500, Bacau, Romania	2. AUDIT DATE 06/01/2004	3. ESTABLISHMENT NO. 02	4. NAME OF COUNTRY Romania
5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		


60. Observation of the Establishment:

Country : Romania  
Date of Audit : 06/01/2004  
Establishment # 02  
Processing

22/51 HACCP monitoring records did not include initial by the responsible establishment employee for each entry {9CFR part 417.5(b)}.

61. NAME OF AUDITOR  
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

 06-14-04



ROMANIA



**AUTORITATEA NATIONALA SANITARA VETERINARA  
SI PENTRU SIGURANTA ALIMENTELOR  
DIRECTIA GENERALA SANITARA VETERINARA**

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

**Nr. 22236 / 27.09.2004**

**UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE**

**To: Sally WHITE, Director, IES, OIA  
Fax : 2026904040**

**Ref : Draft final report – Audit carried out in Romania covering  
Romanian meat inspection system, from May 19 through June 9, 2004**

Regarding the Draft report on the audit of Romanian meat inspection system, from May 19 through June 9, 2004, performed by „Food Safety and Inspection Service” - United States Department of Agriculture experts, we would like to thank you for the recommendations mentioned by the specialists during the audit, and also for those in the draft report.

We take this opportunity to communicate you that the Romanian Central Veterinary Authority transmitted the recommendations to the district veterinary services responsible for the surveillance of the evaluated establishments, in order to enforce the necessary measures.

With high consideration,

**GENERAL DIRECTOR**



**Dr. Ion Sorin MITREA**