



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

NOV 10 2008

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

Dear Dr. Mitrea,

This letter transmits the Food Safety and Inspection Service's (FSIS) final report of a meat inspection system audit conducted in Romania from December 4 through December 17, 2002. FSIS did not receive comments regarding the audit findings outlined in the enclosed final audit report.

If you have any questions or need additional information, please contact me at 202-720-3781, fax 202-690-4040 or email at [sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov).

Sincerely,

Sally Stratmoen, Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

Holly S. Higgins, 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  
Linda Swacina, Deputy Administrator, FSIS  
Karen Stuck, Assistant Administrator, OIA, FSIS  
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Todd Furey, IES, OIA, FSIS  
Richard Brown, IES, OIA, FSIS  
Country File

**FINAL**

OCT 23 2003

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

December 4 through December 17, 2002

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 (National Sanitary Veterinary Agency, Hygiene and Public Health Direction)
FSIS	Food Safety and Inspection Service
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

## 1. INTRODUCTION

The audit took place in Romania from December 4 through 17, 2002.

An opening meeting was held on December 4, 2002 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 Agency, Hygiene and Public Health Direction, and representatives from the regional and local inspection offices.

## 2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two laboratories performing analytical testing on United States-destined product, and two establishments conducting swine slaughter and pork processing.

Competent Authority Visits			Comments
Competent Authority	Central	1	
Laboratories		2	
Meat Slaughter/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 two slaughter establishments that also performed processing. The fourth part involved visits to two government laboratories. The Hygiene and Veterinary Public Health Institute was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species. *Laboratorul Zonal Pentru Controlul Reziduurilor* was conducting analyses of field samples for Romania's national residue control program.

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* species. Romania's inspection system was assessed by evaluating these five risk areas.

During both 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 to the CCA that their meat inspection system would be audited in accordance with three areas of focus. First, the auditor would audit against FSIS regulatory requirements. These include 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 testing, and FSIS' requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella* species

Second, 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 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 for *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* testing - The Government of Romania has a surveillance program for ready-to-eat products for *Listeria* testing (one sample per month), but it is mandatory (every lot) when product is exported to the U.S.
- Equine slaughter in Establishment 68. Equines are no longer being slaughtered in this establishment.

#### 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 [www.fsis.usda.gov/fofo/tsc](http://www.fsis.usda.gov/fofo/tsc).

### November 15 through December 1, 2000:

- There was condensation in product areas and a lack of immediate corrective action in one establishment.
- There were maintenance program deficiencies in an establishment.
- There was improper stunning of swine in one establishment.
- There was no random carcass selection for *E. coli* and *Salmonella* testing in either slaughter establishment.
- In one establishment, the program for enforcing the "zero tolerance" policy for fecal contamination on carcasses was not adequately described in the written program, the written HACCP program did not include verification, and on-site documentation of the CCP in the slaughter operation was not performed in that same establishment.

### October 31 through November 14, 2001:

- The laboratory was not testing for arsenic.
- Pre-shipment review and intended use of finished products were not included in the HACCP plan for Est. 68.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

The National Sanitary Veterinary Agency controls the Hygiene and Veterinary Public Health Department and the National Microbiology Laboratory, which also includes the National Reference Laboratory for Residues Control. Under the control of the Hygiene and Veterinary Public Health Department are 42 District Veterinary Offices. The District Veterinary Offices have control of the individual local or establishment offices for the control of products of animal origin and the state veterinary laboratories.

#### 6.1.1 CCA Control Systems

The Romanian CCA controls were in place for ante-mortem and post-mortem inspection procedures and dispositions; control of restricted product and inspection samples; control and disposition of dead, dying, diseased or disabled animals; boneless meat re-inspection; shipment security, including shipment between establishments; prevention of commingling of product intended for export to the United States with domestic product; monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans); inspection supervision and documentation; the importation of only eligible livestock or poultry from other countries.



### 6.1.2 Ultimate Control and Supervision

Ultimate control and supervision of decisions made at the local and District levels rests with the Hygiene and Public Health Directorate.

### 6.1.3 Assignment of Competent, Qualified Inspectors

Assignment of competent, qualified inspectors is made by the CCA. Inspectors are chosen based on competitive examinations with interviews. Assignments are made by District offices based upon need.

### 6.1.4 Authority and Responsibility to Enforce the Laws

The authority and responsibility to enforce the laws rest with the CCA as they empower the local and District Offices.

### 6.1.5 Adequate Administrative and Technical Support

The CCA of Romania appears to have adequate administrative and technical support staffs.

## 6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at local offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States
- Training records for inspectors and laboratory personnel.
- Label approval records, such as generic labels and animal raising claims.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control, including export certificates.
- Enforcement records 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 following sites were audited:

- Interviewed the Director at the Hygiene and Public Health Direction, Bucharest. This office was audited to learn of controls over the Romania Meat Inspection Service and its role in those controls.
- Interviewed a Veterinary Officer at the Food Hygiene Office of the Hygiene and Public Health Direction, Bucharest. This interview was to learn of the Veterinary Officer's role in the control process of food hygiene and HACCP and SSOP.
- Interviewed the Director at the Hygiene and Veterinary Public Health Institute, Bucharest. This interview was to learn of the procedures and controls of the laboratory with regards to microbiology testing.
- Interviewed the Director at the *Laboratorul Zonal Pentru Controlul Reziduurilor* in Timisoara. This interview to learn of the procedures and controls of the laboratory with regards to residue testing of products of animal origin.
- Interviewed the Director General at Est. 68, Agrotorvis in Timisoara. This interview was to learn of the establishment's understanding of HACCP, SSOP and meat production.
- Est. 2, Agricola International, Bacau. This establishment was audited to learn of the establishment's understanding of HACCP, SSOP and meat production.

The following findings resulted from the audits of these inspection sites.

- The Romanian Meat Inspection officials have a basic understanding of the requirements for HACCP and SSOP, but do not understand their obligations to enforce those regulations.
- The laboratories have good controls over samples and use appropriate procedures, and no deficiencies were found regarding the residue-testing program.
- Although establishment personnel are familiar with HACCP and SSOP terminology, implementation of these requirements was inadequate.
- Establishment personnel do not understand their obligations with regard to carrying out the objectives of the meat inspection program, and how those objectives must be met.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited the two establishments that were certified to export to the U.S. Both establishments were certified for slaughter and processing. One establishment was delisted because of recurring SSOP and HACCP deficiencies.

One establishment received a notice of intent to be de-listed by the Romanian officials because of inadequate implementation of SSOP and HACCP requirements.

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 laboratories were reviewed:

- Hygiene and Veterinary Public Health Institute, Government Reference Laboratory, Bucharest, Romania.
- *Laboratorul Zonal Pentru Controlul Reziduurilor*, Government Residue Laboratory, Timisoara, Romania.

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, and except as noted below, 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, workspace, 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 two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In one establishment's written SSOP, there was no differentiation between pre-operation and operational sanitation.
- Documentation of sanitation activities, findings, and corrective actions was not available for audit.
- Preventive measures were not described.
- In one establishment, sanitation activities, findings, and corrective actions were not being documented.
- In one establishment, preventive measures were incomplete.

## 9.2 Sanitation

The following deficiencies were noted:

- In one establishment, carcasses were routinely contacting an electrical control box that had rust and flaking paint on its surfaces. Immediate corrective actions were not observed.
- In one establishment, an employee dropped meat on the floor, then picked it up and put it into a container with edible product. The product in the container was immediately condemned and the employee made to wash his hands. The container was immediately washed.

## 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 reviews is 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 testing program for generic *E. coli* 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 two establishments. Neither establishment had adequately implemented the HACCP requirements.

- One establishment had a CCP for ante-mortem, but did not indicate whether the observations were acceptable or unacceptable.
- In one establishment, the frequency of the monitoring of two CCPs was not specified in the written HACCP plan.
- In one establishment, documentation of monitoring of three of the four CCPs was not available for audit.
- In one establishment, verification, validation of corrective actions and preventive measures were not completely identified in the HACCP plan and the records for them were incomplete.
- In one establishment, validation and verification were being performed but not documented and preventive measures were inadequate.

### 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.

Both of the establishments were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in one of the two slaughter establishments.

- In one establishment, sampling procedures for testing for generic *E. coli* were not adequate to prevent contamination of the sample.

#### 11.4 Testing for *Listeria monocytogenes*

Both of the establishments 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 both 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 *Laboratorul Zonal Pentru Controlul Reziduurilor* in Timisoara was audited.

No deficiencies were noted.

Romania's National Residue Testing Plan for 2003 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* species.

#### 13.1 Daily Inspection in Establishments

Inspection was being conducted daily in both establishments.

#### 13.2 Testing for *Salmonella*

Romania has adopted the FSIS regulatory 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

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

Testing for *Salmonella* species was properly conducted in both of the two establishments.

### 13.3 Species Verification

Species verification was being conducted in both establishments. 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 both establishments, monthly supervisory reviews of certified establishments were being performed and documented as required.

### 13.5 Inspection System Controls

The CCA had controls in place for 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.

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 December 17, 2002 in Bucharest, Romania, 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.

Judd Giezentanner, DVM  
International Audit Staff Officer

*Judd Giezentanner* 10/22/05

## 15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Audit Forms

Foreign Country Response to Draft Final Audit Report (*no country comments received*)



REVIEW DATE

NAME OF FOREIGN LABORATORY

Dec 6, 2002

Laboratorul Central Pentru Controlul

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 Ministerul Agriculturii Si Alimentatiei  
 Agentia ntionala Sanitar veterinara

CITY & COUNTRY  
 Timisoara, Romania

ADDRESS OF LABORATORY  
 Str. Polona Nr. 4  
 1900 Timisoara, Romania

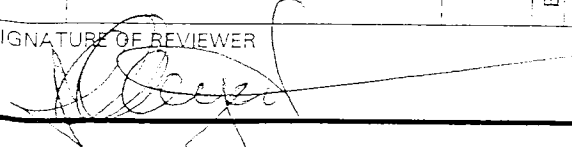
NAME OF REVIEWER  
 Judd Giezentanner, DVM

NAME OF FOREIGN OFFICIAL  
 Sergiu Meica

Residue Code/Name			100	200	300	500	700	400	800	900					
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01	A	A	A	A	A	A	A	A	A				
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A				
	Timely Analyses	03	A	A	A	A	A	A	A	A	A				
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O				
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O				
	Data Reporting	06	A	A	A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES			EVALUATION CODE												
	Acceptable Method	07	A	A	A	A	A	A	A	A	A				
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A				
	Equipment Operation	09	A	A	A	A	A	A	A	A	A				
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES			EVALUATION CODE												
	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A				
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A				
	Percent Recovery	13	A	A	A	A	A	A	A	A	A				
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A				
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A				
	Corrective Actions	16	A	A	A	A	A	A	A	A	A				
	International Check Samples	17	A	A	A	A	A	A	A	A	A				
REVIEW PROCEDURES			EVAL. CODE												
	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A				
OTHER REVIEW PROCEDURES		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

DATE



2/4/05

Dec 10, 2002

Hygiene & Veterinary Public Health Institute

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 Hygiene & Veterinary Public Health Inst

CITY & COUNTRY  
 Bucharest, Romania

ADDRESS OF LABORATORY  
 5 Campul Mosilar St. Sector 2, 73341  
 bucharest Romania

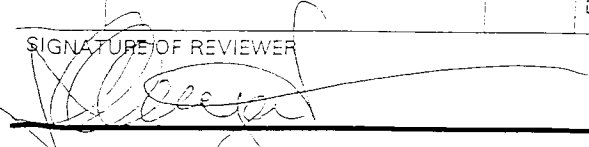
NAME OF REVIEWER  
 Judd Giezantner, DVM

NAME OF FOREIGN OFFICIAL  
 Dr. Anca Ciuciuc

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

SIGNATURE OF REVIEWER

DATE



2/4/03

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agricola International Bacau, Romania	2. AUDIT DATE Dec 10, 2002	3. ESTABLISHMENT NO. Est 2/2A	4. NAME OF COUNTRY Romania
5. NAME OF AUDITOR(S) Judd Giezentanner, 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	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	X
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	X	56. European Community Directives	
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

ROMANIA – Est. 2/2A Dec. 10, 2002

(10) 9 CFR Part 416.13

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 by the employee to recondition or re-inspect the contaminated product.

(12) 9 CFR Part 416.15

Record-keeping requirement not met; i.e., preventive measures not being recorded.

(19) 9 CFR Part 417.5(a)(2)

No decision making documents to support the verification activities or frequencies.

(20) 9 CFR Part 417.3(a)

Written HACCP plan does not address corrective action.

(28) Aseptic techniques were not being followed during the collection of generic *E. coli* samples.

(51) Government inspection officials were not adequately enforcing FSIS requirements.

The auditor requested that the government of Romania issue a Notice of Intent to Delist to this establishment due to observations documented above.

61. NAME OF AUDITOR

Judd Giezantner, DVM

62. AUDITOR SIGNATURE AND DATE

*Judd Giezantner* 10/22/03

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agrotorvis Timisoara, Romania	2. AUDIT DATE Dec. 5, 2002	3. ESTABLISHMENT NO Est. 68	4. NAME OF COUNTRY Romania
5. NAME OF AUDITOR(S) Judd Giezantanner, 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	X	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.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	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.	X	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/Park 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	
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

ROMANIA – Est. 68 Dec. 5, 2002

(7) 9 CFR Part 416.12

The written SSOP did not clearly define what activities would be conducted prior to operations and what activities would be conducted during operations.

(10) 9 CFR Part 416.13

Cattle carcasses were contacting an electrical box that was covered with peeling paint and product residue.

(12) 9 CFR Part 416.15

Record-keeping requirement not met, i.e., preventive measures not being recorded.

(15) 9 CFR Part 417.2(b)(2)

The hazard analysis does not address chemical, physical or biological hazards at each step in the flow diagram.

(16) 9 CFR Part 417.2(c)(4)

The frequencies for which monitoring activities is to be performed is not described in the HACCP plan for CCP 3 and CCP 4.

(18) 9 CFR 417.5(a)(2)

No decision making documents to support the monitoring activities.

(22) 9 CFR Part 417.5(b)(3)

Records are not maintained at the time the event occurs.

(51) Government inspection officials were not adequately enforcing FSIS requirements.

The auditor requested that this establishment be delisted by government officials due to the observations documented above.

61. NAME OF AUDITOR

Judd Giezentanner, DVM

62. AUDITOR SIGNATURE AND DATE

*for Margaret H. Chaudry 10/22/03*

**Country Response Not Received**