



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Gabriel Predoi
Director General
National Sanitary Veterinary Agency
Ministry of Agriculture, Food and Rural Development
1B Negustori Street, Sector 2
Bucharest, Romania

FEB 17 2006

Dear Dr. Predoi:

The Food Safety and Inspection Service conducted an on-site audit of the Romania meat inspection system July 11 through August 2, 2005. Enclosed is a copy of the final audit report. Your draft final report comments have been attached as an addendum to 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.

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

Alina Beldescu, First Secretary of Economic Affairs, Embassy of Romania

James Dever, FAS Area Director

Robert Macke, ITP, FAS

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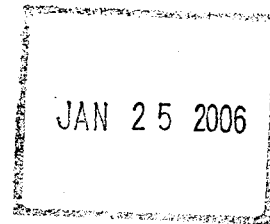
Mary Stanley, Director, IID, OIA, FSIS

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Country File

FINAL



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

JULY 11 THROUGH AUGUST 2, 2005

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
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
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 July 11 through August 2, 2005.

An opening meeting was held on July 11, 2005, 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 National Sanitary Veterinary and Food Safety Authority (NSVFSA), Hygiene and Veterinary Public Health Department (HVPHD), 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, four establishment levels inspection, two laboratories performing analytical testing on United States-destined product, two slaughter establishments, and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Bucharest
	Regional	3	Bihor, Brasov, and Teleorman
	Local	4	Establishment level
Laboratories		2	
Meat Slaughter Establishments		2	
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 and regional offices. The third part involved on-site visits to four establishments: two slaughter establishments and two processing establishments. The fourth part involved a visit to two government laboratories. The Hygiene and Veterinary Public Health Institute in Bucharest was testing for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* and Laboratorul sanitar Veterinar de Stat si Pentru Siguranta

Alimentelor in Constanta 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*. 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.

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

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.

In the audit of May 19 through June 9, 2004, the following findings were observed:

- HACCP monitoring records did not include initial 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.

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 May/June 2004. 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 follow:

- 1) General Sanitary 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 Sanitary Veterinary Directorate is divided into Animal Health Directorate and Hygiene and Veterinary Public Health Directorate (HVPHD). The HVPHD 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 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 individual local or establishment offices for the control of products of animal origin. There is an afferent state veterinary laboratory in each district.

One certified establishment in Brasov's District was delisted during this audit. Currently, Romania has four certified establishments to export to the United States. The government oversight for these establishments is being managed by four district offices in Bihor, Bacau, Teleorman, and Sibiu.

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 HVPHD employs approximately 1200 personnel to carry out the responsibility of its domestic and export meat 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.

6.1.2 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. 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.

The HVPHD 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 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 four certified establishments audited, HVPHD has placed a sufficient number of official inspection personnel to carry out the FSIS and Romania's meat inspection requirements. However, Romania's inspection needs to continue providing training to inspection personnel regarding U.S. inspection requirements including training in government enforcement of the 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.

6.1.4 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.

6.1.5 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.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters, three district offices, and four 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 exported any meat products to the United States for the past several years.

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 HVPHD inspection officials at the three district offices as below:

- Bihor District Office in Oradea
- Brasov District Office in Brasov
- Teleorman District Office in Alexandria

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

7. ESTABLISHMENT AUDITS

Five establishments were certified as eligible to export to the United States at the time of this audit. Due to sudden flooding, one of these establishments was unable to operate and could not be audited. The FSIS auditor visited the other four establishments; two were slaughter establishments and two were processing establishments. One establishment was delisted by Romania. None of the establishments received a notice of intent to delist.

Specific deficiencies are noted in the attached individual establishment reports.

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:

The microbiological section of the Romanian Hygiene and Veterinary Public Health Institute, a government reference laboratory located in Bucharest, was audited.

The residue section of the Laboratorul sanitar Veterinar de Stat si Pentru Siguranta Alimentelor, a government laboratory located in Constanta, was audited. This laboratory was conducting analyses of field samples for Romania's national residue control program.

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. Of the four establishments reviewed, there was inadequate implementation of SSOP requirements in two establishments.

SSOP implementation deficiencies are noted on the attached individual establishment reports.

9.2 Sanitation

The following deficiencies were noted:

- Direct product contamination due to dripping condensation onto exposed swine carcasses and equipment containing edible products in one establishment.

- Two establishments had SSOP record keeping deficiencies.

Specific deficiencies are noted in the attached individual establishment reports.

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 four establishments. All four establishments audited had not adequately implemented the HACCP requirements.

Specific deficiencies are noted in the attached individual establishment reports.

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.

Two of the four establishments audited were 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 properly conducted in two slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

Three of the four establishments audited were producing ready-to-eat products for export to the United States. One establishment was producing ready-to-eat product which was not post-lethality exposed. Two establishments were canning facilities producing thermally processed/commercially sterile products. Romania's inspection system has a surveillance program for ready-to-eat products for *Listeria monocytogenes* testing. It consists of one sample per month for domestic consumption and mandatory sampling of every lot if the product is destined for export.

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 sanitar Veterinar de Stat si Pentru Siguranta Alimentelor, a government residue laboratory located in Constanta, was audited. No deficiencies were noted.

Romania's National Residue Testing Plan for 2005 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.

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

Testing for *Salmonella* was properly conducted in these establishments.

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

Monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

With the following exception in one swine slaughter facility, 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.

- The submaxillary lymph nodes were not incised/examined by the official inspector.
- Swine kidneys and visceras were not being inspected by the official inspector during routine postmortem inspection of each carcass. Kidneys and visceras were presented for veterinary inspection without having any identification number or devices matching the corresponding swine carcasses.

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 August 2, 2005 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.

for Dr. Nader Memarian
Senior Program Auditor

Mangzor H. Chaudry

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Scandia Romana S.A. Sibiu 550197, Str. Morilor NR. 45	2. AUDIT DATE 07/26/2005	3. ESTABLISHMENT NO. 183	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	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	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	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Country : Romania
Date of Audit : 07/26/2005
Establishment # 183
Processing

13/51 The establishment records did not document all three parts of the corrective actions (especially to prevent recurrence) for SSOP deficiencies as required in 9CFR part 416.15.

22/51 A) HACCP records documenting the calibration of process-monitoring equipment did not include the actual value and/or the time the specific event occurred as required in 9 CFR part 417.5.

B) The establishment's records did not address all four parts of the corrective action to be followed in response to a deviation from critical limit as required in 9CFR part 417.3.

61. NAME OF AUDITOR

Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

 08-04-05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Carmolimp S.R.L., Ucea de Jos, Jud. Brasov	2. AUDIT DATE 07/13/2005	3. ESTABLISHMENT NO. A-80	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	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.		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.	X	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	X
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. Delistment	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Country : Romania
 Date of Audit : 07/13/2005
 Establishment # A-80
 Slaughter/Processing

- 7/51 The Sanitation SOP's did not describe all procedures that the establishment will conduct daily, during operation, sufficient to prevent direct contamination or adulteration of product(s) {9 CFR part 416.12}.
- 10/51 Beaded condensation from the over head structures was observed dripping onto exposed:
 1) Swine carcasses in the cooler and 2) equipment (mixer) containing edible products in the processing room {9 CFR part 416.13}.
- 13/51 The establishment did not maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken {9 CFR part 416.16(a)}.
- 15/51 A) The establishment's HACCP plan did not list the verification procedures, and the frequency with which those procedures will be performed in accordance to 9 CFR part 417.4(a)(2) {9 CFR part 417.2 (c) 7}.
 B) The establishment's HACCP plan did not include all four parts of corrective actions in response to any deviation from a critical limit at a critical control point in accordance to 9 CFR part 417.3 {9 CFR part 417.2 (c)5}.
- 22/51 A) The establishment's HACCP monitoring records did not include time and initial by the responsible establishment employee for each entry {9 CFR part 417.5(b)}.
 B) There were no pre-shipment records available for review {9 CFR part 417.5(c)}.
- 55/51 A) The submaxillary lymph nodes were not incised/examined by the official inspector.
 B) Swine kidneys were not being inspected by the official inspector during routine postmortem inspection of each carcass. A pile of swine Kidneys were presented for veterinary inspection without having any identification number or devices matching the corresponding swine carcass.
 C) Swine visceras were not being inspected by the official inspector during routine postmortem inspection of each carcass. A pile of swine visceras were presented for veterinary inspection without having any identification number or devices matching the corresponding swine carcass. Items B and C are not meeting 9 CFR part 310.2 which states, "...all viscera of each slaughtered animal shall be handled in such a manner as to identify them with the rest of the carcass and as being delivered from a particular animal involved, until the post-mortem examination of carcass and parts thereof has been completed.."
- 58 Due to noncompliance with the proper implementation of the postmortem inspection procedures, Basic and ongoing SSOP and HACCP requirements, and lack of enforcement requirements by the Romania's meat inspection officials, the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with Romania's meat inspection officials and they agreed to remove Establishment A-80 from the list of establishments eligible to export meat and meat products to the United States, effective July 13, 2005.

61. NAME OF AUDITOR

Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

Nader Memarian 08-04-05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Cicalex S.A. Str. Abatorului nr. 1- Alexandria	2. AUDIT DATE 07/19/2005	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
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	O
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

Country : Romania
Date of Audit : 07/19/2005
Establishment # 60
Slaughter/Processing

45 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.

22/51 The HACCP verification records did not document the results of ongoing verification as required in 9 CFR part 417.5(a)(3).

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

Nader Memarian 08-04-05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SC Principal Construct Str. Ghestului nr. 10 Salonta-Bihor, Romania	2. AUDIT DATE 07/21/2005	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	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	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Country : Romania
Date of Audit : 07/21/2005
Establishment A-12
Processing

- 19/51 The establishment did not follow its verification frequency for calibration of process-monitoring equipment in accordance to its HACCP plan as required in 9CFR part 417.4.
- 22/51 A) The HACCP verification records did not document the results of ongoing verification as required in 9 CFR part 417.5(a)(3).
B) The HACCP monitoring and verification records did not document the time the specific event occurred as required in 9 CFR part 417.5(b).

61. NAME OF AUDITOR

Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

Nader Memarian, DVM 08-04-05

Country Response Not Received