



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

FEB 6 2002

Dr. Gabriel Predoi  
Director General  
Romanian Veterinary Agency  
Ministry of Agriculture and Food  
Carol I Boulevard, No. 24  
Bucharest, Romania

Dear Dr. Predoi:

Enclosed is the Final report regarding the Food Safety and Inspection Service (FSIS) on-site audit of Romania's meat inspection system. FSIS conducted this audit from November 15 through December 1, 2000. We apologize for the lateness in closing out this audit.

If you have any questions regarding the enclosed report or need additional information regarding this audit, please contact me at telephone number 202-720-3781 or facsimile number 202-720-7990. You also may reach me by email ([sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov)).

Sincerely,

Sally Stratmoen, Chief  
Equivalence Section  
International Policy Staff  
Office of Policy, Program Development  
and Evaluation

Enclosure

cc: Tony Pavel, Agricultural Attaché, American Embassy, Bucharest  
Razvan Dumitrescu, Embassy of Romania, Washington, DC  
Andrew Burst, FAS Area Officer  
Amy Winton, State Department  
Ghias Mughal, Chief, International Review/TSC/FSIS  
Sally Stratmoen, Chief, ES/IPS/OPPDE/FSIS  
Steve McDermott, ES/IPS/OPPDE/FSIS  
Country File (Romania-FY2001 Audit)

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## AUDIT REPORT FOR ROMANIA NOVEMBER 15 THROUGH DECEMBER 1, 2000

### INTRODUCTION

#### Background

This report reflects information that was obtained during an audit of Romania's meat inspection system from November 15 through December 1, 2000. Three establishments certified to export meat to the United States were audited. Two of these were slaughter establishments; the other one was conducting processing operations.

The last audit of the Romanian meat inspection system was conducted in February/March 2000. Three establishments were audited and all three were acceptable. Five major concerns were reported at that time:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is effectively implemented and the frequency with which these procedures will be performed. Neither establishment personnel nor GOR meat inspection officials were performing adequate ongoing verification activities of HACCP program in Establishments 2, 12, and 68. *This was found, during this new audit, to have been adequately corrected.*
2. The HACCP plan needed to be revised to ensure compliance with zero tolerance for visible fecal material on carcasses in Establishments 2 and 68. The requirement of "zero tolerance" for fecal material on carcasses was not enforced by either establishment officials or GOR meat inspection officials and monitoring records were not maintained to verify this activity. *This had been corrected, but in Est. 2/A2, the written procedures for ensuring zero tolerance for fecal contamination were not clearly defined.*
3. Monitoring frequencies and corrective actions followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plans of Establishments 2, 12, and 68. *This had been corrected.*
4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of each shipment eligible for export to the U.S. *This was resolved.*
5. The following information was not recorded in the official record books for Laboratory Quality Assurance Program: lot numbers, expiration dates for standard solutions, reagents, and media ingredients. The record books were not signed and verified by the supervisor before the new solutions were prepared by the technicians or chemists. The

records for corrective actions taken when unacceptable check sample results were reported. *These deficiencies had been adequately addressed and corrected.*

Cattle and pork species and cured (dried) smoked product, cooked sausages and shelf stable canned product is eligible for export to the U.S.

During calendar year 2000, Romanian establishments did not export any meat product to the U.S.

## PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Romanian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of records pertaining to residue control in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing both; analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella* and the other performing only analytical testing of field samples for the national residue testing program

Romania's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

## RESULTS AND DISCUSSION

### Summary

Except as otherwise noted, effective inspection system controls were found to be in place in the three establishments audited; two of these (Est.2/A2 and Est.68) were recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, five major concerns had been identified during the last audit of the Romanian meat inspection system, conducted in February/March 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected.

During the last audit, HACCP-implementation deficiencies had been found in three establishments (Ests. 2/A2, A12, and 68). During this new audit, implementation of the required HACCP programs was again found to be deficient in Est. A/2A; it was now adequate in the other two. Overall, there was improvement in HACCP verification and only the column for verification was missing in the record keeping part of the HACCP programs. Also, the zero tolerance for fecal contamination in their HACCP program was unclear. Details are provided in the Slaughter/ Processing Controls section later in this report.

### Entrance Meeting

On November 17, an entrance meeting was held in the Bucharest offices of the Food Hygiene and Public Health Directorate (FHPHD), National Sanitary Veterinary Agency (NSVA), Ministry of Agriculture and Food (MAF) and was attended by Dr. Marilena Barcan, Director, FHPHD; Dr. Ion Nisipasu, State Inspector; Dr. Anca Ciuciuc, Veterinary Doctor; Dr. Sergiu Meica, Director, the Hygiene and Veterinary Public Institute reference laboratory, and Dr. Oto Urban, International Audit Staff Officer. Topics of discussion included the following:

1. Updates on the inspection system of Romania
2. The audit itinerary and travel arrangements
3. Animal diseases status in Romania according to APHIS
4. Enforcement
5. *Listeria monocytogenes* testing
6. The status of species verification in Romania

### Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Romania's inspection system in February/March 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the meat inspection headquarters. 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 U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- 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, 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 the examination of these documents.

### Government Oversight

All inspection veterinarians and inspectors in establishments certified by Romania as eligible to export meat products to the United States were full-time FHPHD employees, receiving no remuneration from either industry or establishment personnel.

### Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted; all were visited for on-site audits. In all these establishments, both FHPHD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. Except in one case involving Est. 2/A2, corrective actions were prompt and effective. Establishment A12 was acceptable, and establishments 2/A2 & 68) were evaluated as acceptable/re-review.

## Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of certified, or approved laboratories, intra-laboratory quality assurance procedures, including sample handling and methodology.

The Hygiene and Veterinary Public Institute reference laboratory in Bucharest was visited on November 20, 2000, and the Regional Residue Laboratory in Timisoara on November 27, 2000. The reference laboratory in Bucharest was accredited in 1998 by the national accreditation body called RENAR for chemical control, microbiological control and toxicological control.

Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, check sample frequency and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Neither laboratory was testing field samples for arsenic.

Romania's microbiological testing for *Salmonella* species was being performed in government laboratories. One of these, the Hygiene and Veterinary Public Institute laboratory in Bucharest, was audited. No deficiencies were found.

## Establishment Operations by Establishment Number

As previously stated, Romania had not exported any meat to the United States during CY 2000. Thus, any production observed was for domestic use. The following operations were being conducted in the three establishments:

Establishment 2/A2: swine slaughter, boning, cooked sausages, and canned products

Establishment A12: cured and smoked pork products; currently not active producer

Establishment 68: cattle and swine slaughter, boning, cured/dried/smoked products, and canned products; currently not active producer

## SANITATION CONTROLS

Based on the on-site audits of establishments, Romania's inspection system had controls in place for water potability records, chlorination procedure, back siphonage prevention, hand washing facilities, separation of establishments, pest control, temperature control, lighting, operations and inspector work space, ventilation, facilities approval, equipment approval, over-product and product contact equipment, dry storage areas, antemortem and welfare facilities, outside premises, personal dress and habits, personal hygiene practices, sanitary

dressings procedures, cross contamination prevention, product handling and storage, product reconditioning, product transportation, operational sanitation and waste disposal.

### Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

The following sanitation deficiencies were observed:

#### Pre-operational Sanitation

Dirty equipment was found in the bovine slaughter room in Establishment 2/A2. *This was scheduled for correction.*

#### Sanitizers

In Establishment 2/A2, the thermometer for the sanitizers in the slaughter room was found to be non-functional. *Corrective action was immediate.*

#### Effective Maintenance Program

In Establishment 68, the maintenance program was ineffective in that it did not ensure prevention and correction of defects such as rust on chains and on the carcass splitter, dirty hooks (in the swine slaughter area), broken bricks, flaking paint in coolers), residue containing brine in injection needles, dirty aprons in the boning room, and a large gap between an outside door and floor in the export area. This was scheduled for corrective action. In Establishment A12, a few pieces of rusty product-contact equipment were observed in the drying room. They were immediately removed for reconditioning.

### ANIMAL DISEASE CONTROLS

Romania's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit, with the exception of sporadic occurrence of trichinellosis in the small farm areas. No cases of Bovine Spongiform Encephalopathy (BSE) have been reported in Romania, as of the writing of this report. However, according to APHIS, because of import requirements less restrictive than those that would be

acceptable for import into the U.S. and/or because of inadequate surveillance, there is an undue risk of introducing BSE into the U.S.

## RESIDUE CONTROLS

Romania's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Romanian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

GOR inspection service received and completed Residue Questionnaire sent by International Policy Division and discussed the document with the auditor during his laboratory audit.

A visit was made to the farm where pigs were raised and supplied to the establishment in Bacau. The farmers grew their own feed (cereal, corn, soy, fishmeal, and oats). An automatic feed distribution system was used by the company.

The floors and walls were constructed of concrete, and the insulated roof of plastic. The source of the water used was on-site wells. Swine were separated according to age and pens were divided into wet and dry sections. The buildings had heating systems for the winter. There was an accessory electrical heating system for farrowed piglets. Each sow had an identification card and an ear tag.

An official veterinarian was on duty at the farm, and he supervised the company veterinarians. Decisions made by the official veterinarian on any professional issues were final. The official veterinarian was performing the residue sampling and samples were sent to Bucharest and Germany for analysis. Veterinary drugs were kept in the official office; they were registered and under veterinary supervision. Pharmaceuticals were prescribed and administered by veterinarians only.

## SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Romanian inspection system had controls in place to ensure adequate pre-boning trim, boneless meat reinspection, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing schedules and equipment, processing records, empty can inspection, filling procedures, container closure examination, interim container handling, post-processing handling, processing defect actions-plan, and processing control by inspection personnel.

Improper stunning of swine was observed in Est. 2/A2. The operator was not administering electric current properly, with the result that corneal reflexes were present several animals after stunning. Corrective actions were taken immediately by inspection personnel.

## HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with the following major concerns:

1. In Est. 2/A2, the written “zero tolerance” program for fecal contamination was not clearly defined.
2. In Est. 2/A2, HACCP verification was being performed but was missing in the written program.
3. In Est. 2/A2, the documentation for the monitoring of the Critical Control Point in the slaughter operation was missing.

These three deficiencies were scheduled for correction.

## Testing for Generic *E. coli*

Romania had adopted the FSIS regulatory requirements for generic *E. coli* testing.

Two of the three establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements with the following exception:

1. In Ests. 2/A2 and 68, the selection of carcasses for *E. coli* testing was not performed randomly but by pre-selection by the supervisor.
2. In Est. 68, there was no written designation of employees responsible to collect *E. coli* samples.

These deficiencies were corrected immediately.

Additionally, establishments had adequate controls in place to prevent meat products intended for Romania domestic consumption from being commingled with products eligible for export to the U.S.

### Control of *Listeria monocytogenes*

The GOR inspection service had a surveillance program for testing ready-to-eat products for *Listeria monocytogenes*. This testing was mandatory for exported product. In the future, *Listeria* testing will be included in the establishments' HACCP plan.

## ENFORCEMENT CONTROLS

### Inspection System Controls

The Romanian inspection system controls [ante-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 reinspection, 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 (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### Testing for *Salmonella* Species

Two of the three establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Romania has adopted the FSIS regulatory requirements for *Salmonella* testing. The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements with the following exception:

1. In both establishments, there was no HACCP reassessment step, in case of *Salmonella* violation.
2. The samples were not being taken randomly.

The Romanian officials gave assurances that these deficiencies would be corrected promptly.

## Species Verification Testing

At the time of this audit, Romania was not exempt from the species verification requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements. The Romanian officials had applied for exemption from the species verification requirement with International Policy Division (IPD).

## Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

These reviews were being performed by the Romanian equivalent of Circuit Supervisors. All were veterinarians with several years of experience.

The internal review program was applied equally to both export and non-export establishments. Some internal review visits were announced in advance and some were not. They were conducted, at times by individuals and at other times by a team, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in district offices and in the central offices of the National Sanitary Veterinary Agency in Bucharest, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to Drs. Mircea Chertes, General Director, and Marilena Barcan, Director FHPHD, NSVA, for evaluation; they formulate a plan for corrective actions and preventive measures.

GOR has provided training to field inspector on HACCP/PR, and SSOP programs.

## Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision, controls of security items, shipment security, species verification, and product entering the establishments from outside sources.

The GOR inspection service had a regulation to enforce action in the event that an establishment does not meet the *Salmonella* performance standards. The GOR inspection

service, through Veterinary Police, has been detecting and detaining potentially hazardous food in commerce to prevent its consumption.

The procedure for imposing sanctions and fines was established by government decision (Mr. 794/1993), which was recently modified by government decision (605/2000). These sanctions and fines are applied in the case of misdemeanor, and are imposed on the local, regional and central level. Only in the felony case, names of violators can be published. The felony cases are proceeded by court.

### Exit Meetings

An exit meeting was conducted in Bucharest on November 30, 2000. The participants included Dr. Virgil Marcel Eftime, Deputy General Director, NSVA; Dr. Marilena Barcan, Director, FHPHD; Dr. Dana Tanase, Chief, Food Hygiene Service; Dr. Ion Nisipasu, Chief, Food Hygiene Service, FHPHD; Dr. Anca Ciuciuc, Inspector, FHPHD; Dr. Sergiu Meica, Director, the Hygiene and Veterinary Public Health Institute and Dr. Oto Urban, International Audit Staff Officer. The following topics were discussed:

1. Condensation control and lack of immediate corrective action in Est. 2/A2. *The Romanian officials gave assurances that immediate corrective action will be required in the future.*
2. Maintenance program deficiencies in Est. 68. *The GOR inspection officials gave assurances that an improved maintenance program would be implemented and monitored.*
3. Improper stunning of swine in Est. 2/A2. *Corrective action had been immediate.*
4. There had been no random carcass selection for *E. coli* and *Salmonella* testing in either slaughtering establishment. Also, HACCP program reassessment, in case *Salmonella* performance standards are exceeded, required implementation in Est. 2/A2. *Corrective action was programmed by GOR.*
5. In Est. 2/A2, 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 Est. 2/A2. *The GOR officials scheduled corrective actions.*

## CONCLUSION

The inspection system of Romania was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited: one was acceptable, and two were evaluated as acceptable/re-review. The deficiencies

encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Oto Urban  
International Audit Staff Officer

(signed) Dr. Oto Urban

### **ATTACHMENTS**

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (*no comments received*)

**Data Collection Instrument for SSOPs**

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
2/A2	√	√	√	√	√	√	√	√
68	√	√	√	√	√	√	√	√
A12	√	√	√	√	√	√	√	√

### Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
2/A2	√	√	√	√	√	√	√*	√	√	no	√	√
68	√	√	√	√	√	√	√	√	√	√	√	√
A12	√	√	√	√	√	√	√	√	√	√	√	√

2/A2/7\* The "zero tolerance" for fecal contamination needs clarification.

2/A2/10 The written HACCP program needs a verification column

### Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
2/A2	√	√	√	√	√	√	No	√	√	√
68	√	No	√	√	√	√	No	√	√	√

2/A2 & 68/7 No random method specified in the procedure for *E. coli* testing was followed

68/2 The procedure failed to designate the employee responsible to collect samples

**Data Collection Instrument for *Salmonella* testing**

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	<i>1. Testing as required</i>	<i>2. Carcasses are sampled</i>	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
2/A2	√	√	N/A	No	√	√
68	√	√	N/A	No	√	√

2/A2 & 68 The samples were not being taken randomly but by the IIC decision.

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 National Veterinary Agency

CITY & COUNTRY  
 Bucharest, Romania

ADDRESS OF LABORATORY  
 Bucharest, Romania

NAME OF REVIEWER  
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL  
 Dr. Sergiu Meica, Director and Dr. Anca Ciuciuc, Staff Officer

Residue Code/Name			100	111	300	400*	500	200	203	800	923	Sal.	E.co	S/V	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	A	
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A	A	A	
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A	A	A	A	
	Equipment Operation	09	A	A	A	A	A	A	A	A	A	O	O	O	
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A	O	O	O	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A	O	O	O	
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A	O	O	O	
	Percent Recovery	13	A	A	A	A	A	A	A	A	A	O	O	O	
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A	A	A	
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A	A	A	A	
	Corrective Actions	16	A	A	A	A	A	A	A	A	A	A	A	A	
	International Check Samples	17	A	A	A	A	A	A	A	A	A	A	A	A	
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A	A	A	A	
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER

DATE

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		REVIEW DATE 1120/00	NAME OF FOREIGN LABORATORY The Hygiene and Veterinary Public Institute
FOREIGN GOV'T AGENCY National Veterinary Agency	CITY & COUNTRY Bucharest, Romania	ADDRESS OF LABORATORY Bucharest, Romania	
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Sergiu Meica, Director and Dr. Anca Ciuciuc, Staff Officer		
RESIDUE	ITEM	COMMENTS	

400 Arsenic has not been tested in this laboratory.

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 National Veterinary Agency

CITY & COUNTRY  
 Timisoara, Romania

ADDRESS OF LABORATORY  
 Str. Polona nr4, 1900 Timisoara

NAME OF REVIEWER  
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL  
 Dr. N. Chetriesco, Drs. Ion Nicipasu and Anca Ciuciuc

Residue Code/Name		100	111	200	203	400*	500	800	923	S/V				
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	Acceptable Method	07	A	A	A	A	A	A	A	A				
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A				
	Equipment Operation	09	A	A	A	A	A	A	A	A	O			
	Instrument Printouts	10	A	A	A	A	A	A	A	A	O			
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	O			
	Recovery Frequency	12	A	A	A	A	A	A	A	A	O			
	Percent Recovery	13	A	A	A	A	A	A	A	A	O			
	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	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A				
OTHER REVIEW		19												
		20												

SIGNATURE OF REVIEWER

DATE

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		REVIEW DATE 11/27/00	NAME OF FOREIGN LABORATORY Regional Laboratory for Control of Residue
FOREIGN GOV'T AGENCY National Veterinary Agency	CITY & COUNTRY Timisoara, Romania	ADDRESS OF LABORATORY Str. Polona nr4, 1900 Timisoara	
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. N. Chetriesco, Drs. Ion Nicipasu and Anca Ciuciuc		
RESIDUE	ITEM	COMMENTS	

400 Arsenic has not been tested in this laboratory.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY
<b>FOREIGN PLANT REVIEW FORM</b>		11/24/00	Est. 2 Societatea Agricola Comerciala International S.A. (Carbac Bacau)		Bacau
				COUNTRY Romania	
NAME OF REVIEWER Dr. Oto Urban		NAME OF FOREIGN OFFICIAL Drs. Ion Nicipasu & Anca Ciuciuc		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable    M = Marginally Acceptable    U = Unacceptable    N = Not Reviewed    O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 M	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 O	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas ( <i>inside</i> )	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	E. coli & Salmonella	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

<b>FOREIGN PLANT REVIEW FORM</b> (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/24/00	Est. 2 Societatea Agricola Comerciala International S.A. (Carbac Bacau)	Bacau
			COUNTRY
			Romania
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION	
Dr. Oto Urban	Drs. Ion Nicipasu & Anca Ciuciuc	<input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

- 5 Sanitizers' thermometer was found to be not functional in the slaughter room. The corrective action was immediate.
- 7 The presence of flies was observed on the kill floor. Est. Offals made a commitment to correct this problem.
- 17 Non-dripping condensation was observed in the product flow area in the boning room. The corrective action was not immediate.
- 34 Dirty equipment was found in the bovine slaughter room. This was scheduled for correction.
- 40 Improper stunning of swine was observed. The operator was not administering electric current to animals properly. Corneal reflexes were present in several animals after stunning. Establishment committed themselves to correct this deficiency.
- 82 There was no random carcass selection for E. coli & Salmonella testing. The HACCP program reassessment in case of Salmonella testing violation needs to be implemented.
- 83 The written HACCP program's "zero tolerance" for fecal contamination was not clearly defined and HACCP verification was performed but was missing in the written program.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY	
<b>FOREIGN PLANT REVIEW FORM</b>		11/27/00	Est. 68 Societatea Comerciala Comtim Carnex S.A.		Timisoara	
				COUNTRY Romania		
NAME OF REVIEWER Dr. Oto Urban		NAME OF FOREIGN OFFICIAL Drs. Ion Nicipasu anca Ciuciuc		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable		
CODES (Give an appropriate code for each review item listed below) A = Acceptable    M = Marginally Acceptable    U = Unacceptable    N = Not Reviewed    O = Does not apply						
1. CONTAMINATION CONTROL		Cross contamination prevention		28 O	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing		29 O	Packaging materials	56 A
Water potability records	01 A	Product handling and storage		30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning		31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation		32 N	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM			Inspector monitoring	60 A
Sanitizers	05 O	Effective maintenance program		33 M	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation		34 U	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation		35 O	Processing records	63 A
Pest control program	08 A	Waste disposal		36 O	Empty can inspection	64 A
Pest control monitoring	09 M	2. DISEASE CONTROL			Filling procedures	65 A
Temperature control	10 A	Animal identification		37 O	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures		38 O	Interim container handling	67 A
Operations work space	12 O	Antemortem dispositions		39 O	Post-processing handling	68 A
Inspector work space	13 O	Humane Slaughter		40 O	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures		41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions		42 O	Processing control -- inspection	71 A
Equipment approval	16 O	Condemned product control		43 O	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control		44 O	Export product identification	72 O
Over-product ceilings	17 A	Returned and rework product		45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL			Export certificates	74 O
Product contact equipment	19 A	Residue program compliance		46 O	Single standard	75 A
Other product areas ( <i>inside</i> )	20 A	Sampling procedures		47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures		48 O	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.		49 A	Shipment security	78 O
Welfare facilities	23 A	Storage and use of chemicals		50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL			"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim		51 O	Imports	81 O
Personal dress and habits	25 O	Boneless meat reinspection		52 O		
Personal hygiene practices	26 O	Ingredients identification		53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients		54 A		

<b>FOREIGN PLANT REVIEW FORM</b> (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/27/00	Est. 68 Societatea Comerciala Comtim Carnex S.A.	Timisoara
			COUNTRY
			Romania
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION	
Dr. Oto Urban	Drs. Ion Nicipasu anca Ciuciuc	<input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

7/9 This establishment was inactive at the time of the audit. Dead flies and spider webs were observed in many areas of the establishment.

33/34 There was an ineffective maintenance program and preoperational sanitation that did not prevent and correct defects such as rusty and fat containing chains, rusty carcass splitter, dirty hooks (swine slaughter), broken bricks, flaking paint (coolers), residue containing brine injection needles, dirty aprons (boning room), and an enlarged space between outside door and floor in the export area. These deficiencies were scheduled for corrective action.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY
<b>FOREIGN PLANT REVIEW FORM</b>		11/28/00	A 12 Societatea Comerciala Comtim Carnex S.A. Timisoara, Sectia Salamuri crude Salonta		Salonta
NAME OF REVIEWER Dr. Oto Urban		NAME OF FOREIGN OFFICIAL Drs. Ion Nisipasu & Anca Ciuciuc		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below)					
A = Acceptable   M = Marginally Acceptable   U = Unacceptable   N = Not Reviewed   O = Does not apply					
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Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
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(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 M	Control of restricted ingredients	54 A		

<b>FOREIGN PLANT REVIEW FORM</b> (reverse)	REVIEW DATE 11/28/00	ESTABLISHMENT NO. AND NAME A 12 Societatea Comerciala Comtim Carnex S.A. Timisoara, Sectia Salamuri crude Salonta	CITY Salonta
			COUNTRY Romania
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Drs. Ion Nisipasu & Anca Ciuciuc		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

19 Some product holding sticks were found rusty in the smokehouse. deficiency was corrected immediately by the establishment management.

**Country Response Not Received**