



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Handwritten signature

JUN 1 2006

Dr. Vida Čadonič - Špelič, DVM
Chief Veterinary Officer
Veterinary Administration of the Republic of Slovenia
Ministry of Agriculture, Forestry, and Food
Parmova 53
1000 Ljubljana
Republic of Slovenia

Dear Dr. Čadonič - Špelič:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Republic of Slovenia meat inspection system from November 2 through 14, 2005. Enclosed is a copy of the final audit report. No comments regarding the draft final report were received from Slovenia for inclusion with the report.

If you have any questions regarding the FSIS audit, please contact me at telephone (202) 720-3781. You may also reach me at my facsimile number (202) 690-4040 or e-mail address (sally.white@fsis.usda.gov).

Sincerely,

Sally White JD

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Quintin Gray, Counselor, US Embassy, Vienna

Tadej Furlan, Acting Trade and Economics Counselor, Embassy of the Republic of Slovenia

Canice Nolan, Agric. / Consumer Affairs, E.U. Mission to the U.S.

Norval Francis, Minister-Counselor, U.S. Mission to the E.U.

Robert Macke, Assistant Deputy Administrator, ITP, FAS

James Dever, FAS Area Director

Amy Winton, State Department

Barbara Masters, Administrator, FSIS

Linda Swacina, Executive Director, Food Safety Institute of the Americas, OIA, FSIS

Karen Stuck, Assistant Administrator, OIA, FSIS

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Donald Smart, Director, Review Staff, OPEER, FSIS

Sally White, Director, IES, OIA, FSIS

Clark Danford, Director, IEPS, OIA, FSIS

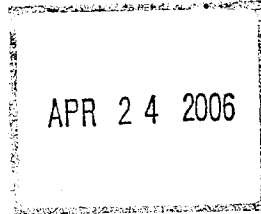
Mary Stanley, Director, IID, OIA, FSIS

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Country File (Republic of Slovenia, FY 2006)

FINAL



FINAL REPORT OF AN AUDIT CARRIED OUT IN THE
REPUBLIC OF SLOVENIA COVERING SLOVENIA'S MEAT
INSPECTION SYSTEM

NOVEMBER 2 through 14, 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 – Veterinary Administration of the Republic of Slovenia
VARS	Veterinary Administration of the Republic of Slovenia
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
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
<i>Lm</i>	<i>Listeria monocytogenes</i>
NVI	National Veterinary Institute
PHIM	Public Health Institute Maribor
DPVH	Department for Veterinary Public Health

1. INTRODUCTION

The audit took place in the Republic of Slovenia from November 2 through November 14, 2005.

An opening meeting was held on November 2, 2005 in Ljubljana, Slovenia with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of Slovenia's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the Veterinary Administration of the Republic of Slovenia (VARs), and/or representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

The objective of the audit was to verify whether Slovenia had implemented the FSIS import inspection requirements, including HACCP and *Salmonella* testing. In addition, there were special emphasis in-depth audits of the microbiological and residue testing systems and associated laboratories.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one regional inspection office, four laboratories performing analytical testing on United States-destined product, and one swine slaughter and processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	1	
	Local	1	Establishment level
Laboratories - Residue		2	
Laboratories - Microbiology		2	
Meat Slaughter and Processing Establishments		1	

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 one regional office. The third part involved an on-site visit to one slaughter and processing establishment. The fourth part involved visits to four contract laboratories. The National Veterinary Institute (NVI), Unit for Food of Animal Origin in Ljubljana and the National Veterinary Institute, Unit Murska Sobota Diagnostic Laboratory were conducting analyses of field samples for the presence of *Enterobacteriaceae* and *Salmonella*. The National Veterinary Institute in Ljubljana and the Public Health Institute in Maribor were conducting analyses of field samples for Slovenia's national residue control program.

Program effectiveness determinations of Slovenia'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*. Slovenia's inspection system was assessed by evaluating these five risk areas.

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

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

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

Currently, the only equivalence determination Slovenia has requested is in regards to the testing for *Enterobacteriaceae* species and total viable count by the European Commission Decision (2001/471/EC) in place of the generic *Escherichia coli* (*E. coli*) testing program.

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.

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

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

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

The previous two FSIS audits of Slovenia's meat inspection system were conducted on: July 28-August 1, 1997 and November 2-6, 1998.

- Hazard Analysis and Critical Control Points (HACCP) Implementation was not yet required as of the date of the last audit because of the size of the establishment.
- No deficiencies regarding the *Escherichia coli* (*E. coli*) testing program were reported as a result of the FSIS audits of July-August 1997 and November 1998. The program was being conducted by inspection personnel at that time but was scheduled to be turned over to the establishment as of January 1999.
- The *Salmonella* species testing program was not yet being conducted at the time of the last audit. This program was scheduled to begin in January 1999.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Slovenia's legislation.

6.2 Government Oversight

In 1999, Slovenia voluntarily delisted establishment No. 22, Pomurka, Mesna industrija d.d., from exporting to the United States because Slovenia did not implement the HACCP and *Salmonella* testing requirements as required by the FSIS Pathogen Reduction/HACCP Final Rule. Slovenia is currently suspended from exporting meat product to the United States.

The competent authority carrying out the administrative tasks, inspection, and control in the veterinary sector is the Veterinary Administration of the Republic of Slovenia (VARŠ), a body within the Ministry of Agriculture, Forestry and Food. VARŠ responsibilities include the preparation of appropriate legislation, control of contagious animal diseases, preparing and providing for the implementation of residue programs for foodstuffs and feed, providing zoonoses control, animal welfare and international trade.

The Chief Veterinary Officer (CVO) is responsible to the Minister of Agriculture, Forestry and Food (MAFF). The Internal Veterinary Inspection Sector is directly responsible to the CVO. There are 10 Regional Offices, five of which have Branch Offices. These Regional Offices are responsible for the Veterinary Inspection Service within meat slaughter and processing establishments. The Border Veterinary Inspection Sector, also a part of MAFF, has six border inspection offices. The Public Health Sector prepares national veterinary legislation governing the production of foodstuff. This Sector also prepares instructions for VARS officers and programs of surveillance in the production of foodstuffs of animal origin. The Public Health Sector is responsible for the grant of approval for establishments to export and organizing and providing training for veterinary personnel.

6.2.1 CCA Control Systems

In the Veterinary Practice Act, Part III is titled Veterinary Preventive Measures. In Article 31 of this Part are the procedures for the classification and registration of facilities. Without this registration, a facility cannot operate. Articles 50-57 define the structure of Veterinary Science for Slovenia. Article 81 defines the structure of VARS.

6.2.2 Ultimate Control and Supervision

Articles 27 and 81 of Part III of the Veterinary Practice Act define VARS as having ultimate control and supervision of the official activities of veterinary inspection in the Republic of Slovenia.

6.2.3 Assignment of Competent, Qualified Inspectors

Article 82 of Part III of the Veterinary Practice Act defines the professional conditions of employment for an employee of VARS. Article 86 gives the official designations for employees of VARS and Article 87 defines the competence required of these employees in various positions.

6.2.4 Authority and Responsibility to Enforce the Laws

Articles 84 and 87 of Part III of the Veterinary Practice define the authority and responsibility of VARS to enforce the laws and regulations governing meat inspection. Articles 17 and 87 #30 define export responsibilities of VARS. Exports are also covered by Council Directive 96/93/EC of 17 December 1996. In the Veterinary Practice Act in Republic of Slovenia 33/2001 and under Veterinary Preventive Measures Article 17 parts 2, 3, and 5 are other requirements and responsibilities. The Procedures for Veterinary Documents Directive State 323-491/2003, gives all of the specific procedures for certificates for export.

- A Notice of Intent to Delist (NOID) would have been given if the establishment had been presently eligible to export to the United States.

6.2.5 Adequate Administrative and Technical Support

Article 83 of Part III of the Veterinary Practice Act gives the definition of required administration of VARS. Article 84 defines the scope of inspection and supervision.

The following contract microbiology laboratories were reviewed:

- The National Veterinary Institute (NVI), Unit for Food of Animal Origin, located in Ljubljana.
- The NVI, Unit Murska Sobota Diagnostic Laboratory located in Murska Sobota.

The following deficiencies were noted:

- When sample testing is performed for *Salmonella*, the test portion is 25 grams, not the 325 grams required by the FSIS testing method.
- The temperature of samples was not routinely recorded at sample receipt in either of the two contract laboratories audited.
- In testing for the presence of *Salmonella* on porcine carcasses, Slovenia uses the ISO 6579 (version 2002) method. Slovenia needs to submit this method to FSIS for an equivalence determination. Until an FSIS equivalence determination is made, Slovenia must implement for pork products being exported to the United States the FSIS laboratory testing method for *Salmonella*.
- Slovenia currently performs canned foods testing for *Clostridium botulinum* using a laboratory testing method that had not been properly validated. Slovenia must use a validated laboratory testing method for *Clostridium botulinum*.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of VARS, the Regional Office at Murska Sobota, and the inspection office in the slaughter and processing establishment visited in Murska Sobota. 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.
- 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.
- 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.

The following concerns arose as a result the examination of these documents.

- The guidelines for the development of SSOPs did not specify a retention time for the records of at least six months.

- The guidelines did not require maintenance and evaluation of the effectiveness of the SSOPs.
- The *Salmonella* testing program did not meet U.S. requirements.
- None of the contract laboratories have been audited by the Veterinary Administration of the Republic of Slovenia (VARs) at this point in time. There is a plan to begin this auditing of the laboratories after January 1, 2006.
- There was a lack of the enforcement of U.S. requirements noted at all levels audited including the laboratories.

6.3.1 Audit of Regional and Local Inspection Sites

The Regional Office of the Veterinary Administration of the Republic of Slovenia (VARs) in Murska Sobota was audited. Present at this audit were the Head of the Department for Public Veterinary Health (DPVH) in VARs, the Chief of Inspection for VARs, the Head of the Department for Health Care and Animal Production (DHCAP) who is also the Deputy Head of the Regional Office, and the Head of the Official Veterinarians for Establishment 22, Pomurka Mesna industrija in Murska Sobota. This office was audited because it has direct oversight of Establishment 22, to determine the conditions of that oversight and to audit documents at this level.

The VARs inspection office at Establishment 22 in Murska Sobota was audited. Present at this audit were the Head of the DPVH in VARs, a member of the Internal Audit Staff as a representative of the Chief of Inspection, the Head of the DHCAP who is also the Deputy Head of the Regional Office at Murska Sobota, and the Head of the Official Veterinarians for Establishment 22. This office was audited for documents created and maintained at this level.

There were no significant findings at this level that are not reflected elsewhere in this report.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited one slaughter and processing establishment. This establishment would have received a Notice of Intent to Delist (NOID) the establishment from the inspection service of Slovenia had it been certified to export at this time. The NOID would have been issued for findings in the implementation of Sanitation Controls and HACCP. Slovenia is at present suspended from exporting meat products to the United States.

Specific deficiencies are noted on the attached individual establishment report.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the 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 evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following contract microbiology laboratories were reviewed:

- The National Veterinary Institute (NVI), Unit for Food of Animal Origin, located in Ljubljana.
- The NVI, Unit Murska Sobota Diagnostic Laboratory located in Murska Sobota.

The following contract residue laboratories were reviewed:

- The National Veterinary Institute (NVI) located in Ljubljana at the University of Ljubljana.
- The Public Health Institute Maribor located in Maribor.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audit of the establishment, and except as noted below, Slovenia'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 and practices, and good product handling and storage practices.

In addition, and except as noted below, Slovenia'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

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the establishment was found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- The evaluation for effectiveness of the SSOPs was only swab testing of equipment and surfaces for total plate count.
- The VARS document outlining SSOP requirements did not have a records retention period specified. There also was no provision requiring evaluation and maintenance of the SSOPs by the establishment.

- The pre-operational checklist only had one small block per day which would not allow for adequate documentation of non-compliances or corrective actions. There was no documentation for operational sanitation except a once per week employee hygiene check. The descriptions of non-conformances were brief and did not adequately describe the findings. In most cases no corrective actions were recorded. Also no preventive measures were documented.

9.2 EC Directive 64/433

In the one establishment audited, the provisions of EC Directive 64/433 were effectively implemented except for the following deficiencies:

- One platform did not have a kick-plate, thus allowing for potential cross-contamination between employee boots and the heads of the pigs passing by on the rail.
- One cooler had ice on the ceiling, walls and floor. There was no product in it at the time.

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, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Slovenia'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.

Slovenia is only eligible to export fully cooked pork products to the United States.

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, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for *Enterobacteriaceae* in slaughter establishments.

11.1 Humane Handling and Humane 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 audit of the one establishment. This establishment had not adequately implemented the HACCP requirements. The following deficiencies were noted:

- Not all hazards (biological, chemical, physical) were recorded as considered for each step of the flow chart in the hazard analysis. There was no CCP developed for zero tolerance of visual fecal, ingesta or milk contamination of the carcasses.
- There were no verification activities listed in the HACCP plan, however, instrument calibration was occurring and records of these actions were kept.
- There was no program for documenting pre-shipment review. CCP monitoring records did not contain initials for each entry, and some entries were an average of several values rather than each value being individually recorded.

11.3 Testing for Generic *E. coli*

Slovenia has not adopted the FSIS regulatory requirements for testing for generic *E. coli* but instead conducts the equivalent testing for *Enterobacteriaceae* species and total viable count by the European Commission Decision (2001/471/EC).

The one establishment audited was required to meet this equivalent program.

Testing for *Enterobacteriaceae* was properly conducted in the one slaughter establishment audited.

11.4 Testing for *Listeria monocytogenes*

The one establishment audited was not producing ready-to-eat products for export to the United States. *Listeria monocytogenes* testing is not required for the one product (commercially-sterile canned ham) that was presented for export. The laboratory does have the capability for *Lm* testing.

11.5 EC Directive 64/433

In the one establishment audited, the slaughter and processing provisions of EC Directive 64/433 were effectively implemented.

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 National Veterinary Institute, located at the University of Ljubljana in Ljubljana, a contract laboratory, was audited. The Public Health Institute Maribor, a contract laboratory located in Maribor, was also audited.

The following deficiencies were noted:

- The temperature condition of a sample at receipt was not recorded at either laboratory audited.
- Many of the methods in use were not fully validated at either laboratory audited. Therefore, much of the information on recovery frequency and percent recovery was not available.
- Many of the methods in both laboratories used different instrumentation than the U.S. methods.
- Many of the methods in both laboratories used different matrices than the U.S. methods.
- Control charts were not available for all compounds analyzed in either laboratory.
- The frequency of check samples was less than would be expected in both laboratories.
- VARS did not audit any of the contract laboratories.
- Because many of the confirmatory analyses were done by the contract laboratory, Chelab in Italy, much of the methodology was unavailable for audit in either laboratory.
- In the training programs in both laboratories, analyses did not always include a true blank and true unknowns.
- In one laboratory, the temperature log for sample receipt was not documented properly.
- In one laboratory, samples which had a potential for court action were not stored in a locked container.
- No control charts were available for meat for one residue in one laboratory.
- In some instances, analytical samples were stored in close proximity to standards.

Slovenia's National Residue Control Program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In the National Veterinary Institute in Ljubljana, the provisions of EC Directive 96/22 were effectively implemented.

In the Public Health Institute Maribor, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Veterinary Institute in Ljubljana, the provisions of EC Directive 96/23 were effectively implemented.

In the National Veterinary Institute in Ljubljana, the provisions of EC Directive 96/23 were effectively implemented.

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 the one slaughter and processing establishment audited.

13.2 Testing for *Salmonella*

Slovenia has not adopted the FSIS regulatory requirements for testing for *Salmonella*.

The one establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

- The present *Salmonella* testing program does not meet the U.S. requirements. The program calls for testing one carcass two times per month continuously and requires corrective action by the establishment following any positive result. The test is done on lymph nodes rather than carcass surfaces as required by the U.S. regulations.
- There is presently no designation of samples that are from U.S. export intended products.
- A program following the U.S. regulations will be put into effect until an equivalence determination can be requested and acted upon. A carcass sampling program for *Salmonella* is required in the new EC regulations that take effect January 1, 2006.

13.3 Species Verification

Species verification was not being conducted in those establishments in which it was required. However, one of the contract laboratories has the capability of performing the testing and currently does it on a client request basis. These tests were conducted by both the establishment and VARS in the past when the establishment was exporting meat products to the United States. VARS does not presently have a plan for species verification testing.

13.4 Monthly Reviews

Monthly supervisory reviews were not being conducted at this time. Slovenia is presently suspended from exporting meat products to the United States; therefore product for U.S. export is not being produced. In this situation, monthly supervisory reviews are not required. VARS assured the lead auditor that these reviews would begin after January 1, 2006, before any product is produced for U.S. export, and that a program and checklists for these monthly supervisory reviews were in the process of development.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

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


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

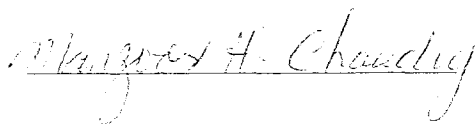
Inspection system controls at all levels were not fully developed and implemented to provide the necessary controls for the production of product for export to the United States. Although at least weekly visits to the establishment were conducted, there was no documentation except for a committee-conducted annual review. VARS does contain an internal audit staff. U.S. regulations, directives and notices were sporadically available at the various offices. Also, a Notice of Intent to Delist would have been given if the establishment had been presently eligible to export to the United States.

14. CLOSING MEETING

A closing meeting was held on November 14, 2005 in Ljubljana, Slovenia with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

 Rori K. Craver, DVM
Senior Program Auditor

 Margaret H. Chaudley

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

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

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Pomurka, Mesna industrija d.d. Panonska 11 9000 Murska Sobota Slovenija	2. AUDIT DATE 8 Nov 2005	3. ESTABLISHMENT NO. 22	4. NAME OF COUNTRY Republic of Slovenia
5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	X
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.	X	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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	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.	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	
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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions	X	59.	
31. Reassessment	X		
32. Written Assurance	X		

80. Observer of the Establishment:

8 November 2005
Est. 22
Pomurka, Mesna industrija d.d.
9000 Murska Sobota
Slovenia

11/51. The evaluation for effectiveness of the SSOPs was only swab testing of equipment and surfaces for total plate count. 9 CFR § 416.14, 9 CFR § 416.17

13/51. Pre-operational checklist only had one small block per day which would not allow for adequate documentation of non-compliances or corrective actions. There was no documentation for operational sanitation except a once per week employee hygiene check. The descriptions of non-conformances were brief and did not adequately describe the findings. In most cases no corrective actions were recorded. Also no preventive measures were documented. 9 CFR § 416.16, 9 CFR § 416.17

15/51. Not all hazards (biological, chemical, physical) were recorded as considered for each step of the flow chart in the hazard analysis. There was no CCP developed for zero tolerance of visual fecal, ingesta or milk contamination of the carcasses. 9 CFR § 417.2, 9 CFR § 417.8

19/51. There were no verification activities listed in the HACCP plan, however, instrument calibration was occurring and records of these actions were kept. 9 CFR § 417.4, 9 CFR § 417.8

22/51. There was no program for documenting pre-shipment review. CCP monitoring records did not contain initials for each entry, and some entries were an average of several values rather than each value being individually recorded. 9 CFR § 417.5, 9 CFR § 417.8

30/31/32/51. The *Salmonella* sampling program currently in use in Slovenia samples lymph nodes, not carcass surfaces. A program following the US regulations will be put into effect until an equivalence determination can be requested and acted upon. 9 CFR § 310.25

34/51. There is currently no species verification testing program in the Veterinary Administration of the Republic of Slovenia (VARS). When this establishment was previously shipping to the US, duplicate samples were taken by the establishment and VARS and analyzed in the Veterinary Institute in Ljubljana. 9 CFR § 327.2

39. One platform did not have a kick-plate, thus allowing for potential cross-contamination between employee boots and the heads of the pigs passing by on the rail. 9 CFR § 416.2, EC Dir. 64/433

41/51. One cooler had ice on the ceiling, walls and floor. There was no product in it at the time. 9 CFR § 416.2, EC Dir. 64/433

*58. In discussion with the VARS officials following the audit, it was agreed that had this establishment been certified to export, they would have received a Notice of Intent to Delist (NOID). VARS will be issuing a notice to the plant of findings necessary to correct.

81. NAME OF AUDITOR

Roni K. Craver, DVM

82. AUDITOR SIGNATURE AND DATE

