



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Dr. Mate Brstilo  
Chief Veterinary Officer  
Veterinary Administration  
Ministry of Agriculture and Forestry  
Ulica grada Vukovara 78  
HR-10000 Zagreb

JUL 23 2004

Dear Dr. Brstilo:

This letter transmits the final report of the Food Safety and Inspection Service's system audit of Croatia's meat inspection system conducted March 4 through 19, 2004. Comments from the government of Croatia have been included in the final report.

If you have any questions or need additional information regarding the enclosed report, please contact me at telephone number (202) 720-3781, facsimile number (202) 690-4040 or email address ([sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov)).

Sincerely,

Sally White, Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

Robert Curtis, Minister Counselor, US Embassy, Vienna

Givko Gubelina, Economic Counselor, Croatia Embassy

James Dever, FAS Area Officer

Amy Winton, State Department

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Donald Smart, Director, Program Review, OPEER, FSIS

Sally White, Director, IES, OIA, FSIS

Clark Danford, Director, IEPD, OIA, FSIS

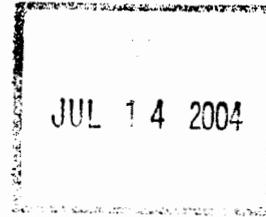
Mary Stanley, Director, IID, OIA, FSIS

Todd Furey, IES, OIA, FSIS

Jack Mowbray, IES, OIA, FSIS

Country File

**FINAL**



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

MARCH 4 THROUGH MARCH 19, 2004

Food Safety and Inspection Service  
United States Department of Agriculture

## TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
  - 6.1 Government Oversight
  - 6.2 Headquarters Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
  - 9.1 SSOP
  - 9.2 Sanitation
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
  - 11.1 Humane Handling and Slaughter
  - 11.2 HACCP Implementation
  - 11.3 Testing for Generic *Escherichia coli*
  - 11.4 Testing for *Listeria monocytogenes*
12. RESIDUE CONTROLS
13. ENFORCEMENT CONTROLS
  - 13.1 Daily Inspection
  - 13.2 Testing for *Salmonella*
  - 13.3 Species Verification
  - 13.4 Monthly Reviews
  - 13.5 Inspection System Controls
14. CLOSING MEETING
15. ATTACHMENTS TO THE AUDIT REPORT

## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority, Ministry of Agriculture, Forestry and Water Management Veterinary Administration
MAFVM	Ministry of Agriculture, Forestry and Water Management
MAFVMVA	Ministry of Agriculture, Forestry and Water Management Veterinary Administration
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

## 1. INTRODUCTION

The audit took place in Croatia from March 4 through March 19, 2004.

An opening meeting was held on March 4, 2004, in Zagreb, Croatia 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 Croatia's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Ministry of Agriculture, Forestry and Water Management Veterinary Administration (MAFVMVA) and/or representatives from the county 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, one county inspection office, four establishment level inspection offices, three laboratories performing analytical testing on United States-destined product, two slaughter and processing establishments, and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	County	1	
	Local	4	Establishment level
Laboratories		3	
Meat Slaughter and Processing 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 or regional offices. The third part involved on-site visits to four establishments: two slaughter and processing establishments and two processing establishments. The fourth part involved visits to two government laboratories and one private laboratory. Both the Croatian Veterinary Institute Regional Laboratory at Križevci and the Central Physical and Chemical Laboratory of Podravka along with the Microbiological Section of the Laboratory of Podravka were conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. The

Croatian Veterinary Institute at Zagreb was conducting analyses of field samples for Croatia's national residue control program.

Program effectiveness determinations of Croatia'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*. Croatia'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 Croatia 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 Croatia's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Croatia. 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 Croatia under provisions of the Sanitary/Phytosanitary Agreement.

Currently, the only equivalence determination Croatia has requested regards the collection and testing of *Salmonella* samples. FSIS has determined that Croatia's collection of samples by the establishments and testing of samples by private laboratories are equivalent to FSIS' requirements.

#### 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/ForeignAuditReports/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/ForeignAuditReports/index.asp)

The last FSIS audit of Croatia's meat inspection system was conducted in January 2002. The following deficiencies were identified:

- In both establishments, critical limit observations were not being recorded as actual values.
- In both establishments, verification and validation were not clearly delineated.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

The Croatian Veterinary Service is vertically structured with the Ministry for Agriculture, Forestry and Water Management above the Veterinary Directorate. From the Veterinary Directorate there are side branches to the five State veterinary Institutions for clinical support, laboratory diagnosis and food control testing, i.e., the Croatian Veterinary Institute, the Faculty of Veterinary Medicine at the University of Zagreb, the Center for Reproduction in Livestock Breeding and the Veterinary Chamber. Leading directly from the Veterinary Directorate are the Veterinary Inspection Officers at Border Stations and the District Veterinary Officers at 20 District Offices and the City of Zagreb. These District Veterinary Offices directly oversee the Authorized Veterinary Inspectors.

#### 6.1.1 CCA Control Systems

There is a Program for Inspection Activities issued each year by the Veterinary Administration with a minimum frequency of inspection activities in the field. There can be no part-time government employees and full-time government employees cannot perform private, establishment-paid tasks, thereby avoiding a possibility of conflict-of-interest.

#### 6.1.2 Ultimate Control and Supervision

The above structure is outlined in the Veterinary Law (Official Gazette No. 71/1997, 105/2001 and 172/2003). All of the Authorized Veterinarians at each level are hired by the MAFVM. The program for the year allows for additional inspection control as needed.

#### 6.1.3 Assignment of Competent, Qualified Inspectors

The Directorate employs about 30 veterinarians in the Headquarters in Zagreb, 60 veterinary inspectors in the border crossing stations, 80 county (district) veterinary inspectors and the rest of the 920 authorized veterinarians are various positions in animal health, public health, meat, poultry and milk inspection as well at the various laboratory facilities.

#### 6.1.4 Authority and Responsibility to Enforce the Laws

The official veterinarian is a veterinarian authorized to perform those tasks of the state administration which have been transferred to authorized veterinary organizations. The Minister, at the proposal of an authorized veterinary organization, appoints authorized veterinarians. The MAFVM gives the authorization to official veterinarians. There is a new Food Law which also provides some of the necessary guidance which is titled Food Law (Official Gazette No. 117/2003). This Food Law brings clearer definition of the responsibilities of both veterinary and sanitary inspection in terms of responsibilities for official control of food of animal origin.

#### 6.1.5 Adequate Administrative and Technical Support

Croatia's MAFVM has adequate administrative and technical support and has the ability to support a third party audit.

### 6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at CCA headquarters in Zagreb. 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.
- 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.
- Enforcement records, including consumer complaints, recalls, seizure and control of noncompliant product.

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

#### 6.3.1 Audit of Regional and Local Inspection Sites

The auditor conducted a review of inspection system documents at the County Headquarters in Križevci with the County Veterinary Inspector/Supervisor and also with the Veterinarian-in-Charge at each of the four establishments visited. These four establishments are located in Vrbovec, Koprivnica (2), and Petrinja. Besides copies of most of the above listed documents, the following other documents were audited:

- Label approval records.
- Records of condemned and inedible product and their disposition.
- Export product inspection and control records including export certificates.

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

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four establishments, two slaughter and processing establishments and two processing establishments. None of the establishments were delisted by Croatia. None of the establishments received a notice of intent to de-certify the establishment from Croatia.

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

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were reviewed:

The Croatian Veterinary Institute at Zagreb and the Croatian Veterinary Institute Regional Laboratory at Križevci, both part of the Croatian government were audited. The Central Physical and Chemical Laboratory of Podravka along with the Microbiological Section of the Laboratory of Podravka, a private company laboratory, were also audited. Training records for lab personnel were provided at each Laboratory.

No deficiencies were noted.

## 9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, Croatia'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, and except as noted below, Croatia's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

## 9.1 SSOP

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

- In one establishment, some corrective action records did not include all three actions, especially preventive actions.
- In one establishment, no records were kept for operational sanitation.

## 9.2 Sanitation

The following deficiencies were noted:

- Spider webs were noted in several areas high above the rails and pans of the porcine slaughter area in one establishment.
- There was light intensity of 42-43 foot candles at two inspection stations in one establishment.
- Condensation was observed on the rails and ceiling of the beef processing room in one establishment.
- The soap at the hand sinks in the dressing rooms of one establishment was too thick to pass through the dispensers.

## 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 Croatia'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. The following deficiencies were noted:

- Two establishments had not adequately implemented the HACCP requirements.
- Verification in the HACCP plans did not include all three parts of verification.
- There was some incomplete documentation of corrective actions on HACCP forms.

#### 11.3 Testing for Generic *E. coli*

Croatia has adopted the FSIS regulatory requirements for generic *E. coli* testing.

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

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

#### 11.4 Testing for *Listeria monocytogenes*

Two of the four establishments audited were producing ready-to-eat products for export to the United States. The products presently exported to the U.S. are fully cooked canned products and not exposed to the environment after heat treatment. Therefore, testing for *Listeria monocytogenes* is not required by FSIS.

### 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 Croatian Veterinary Institute at Zagreb, a part of the Croatian government was audited.

No deficiencies were noted.

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

### 13. ENFORCEMENT CONTROLS

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

#### 13.1 Daily Inspection in Establishments

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

#### 13.2 Testing for *Salmonella*

Croatia has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

- *Salmonella* samples are collected by the establishments and analyzed in private laboratories.

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 both of the slaughter establishments.

#### 13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

#### 13.4 Monthly Reviews

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

#### 13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between

establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

In addition, controls were in place in those establishments presently exporting to the US 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. The MAFVMVA will assure that these controls are in place for the other establishments when they have a product eligible for export to the US.

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 March 19, 2004, in Zagreb, Croatia with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Aurora K. Craver, DVM  
International Audit Staff Officer

*For Manjoo H. Chaudry*

## 15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Individual Laboratory Audit Forms

Foreign Country Response to Draft Final Audit Report

REVIEW DATE  
 03/05/04

NAME OF FOREIGN LABORATORY  
 Croatian Veterinary Institute

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY  
 Croatian Veterinary Administration

CITY & COUNTRY  
 Zagreb, Croatia

ADDRESS OF LABORATORY  
 Savska c. 143  
 10000 Zagreb, Croatia

NAME OF REVIEWER  
 Rori K. Craver, DVM

NAME OF FOREIGN OFFICIAL  
 Dr. Davorin Bazulic, Branko Sostaric, DVM

Residue Code/Name			chc	abc	op	te	des	sulf	iver	clen	chlo	car	spe	Lm	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A	
	Sample Handling	01													
	Sample Frequency	02													
	Timely Analysis	03													
	Compositing Procedure	04													
	Interpret Comp Data	05													
Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	A		
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	C	
	Correct Tissue(s)	08		A	A	A	A	C	A	A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	A	A	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	O	
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A	A	O
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	A	A	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	O
International Check Samples	17	A	O	O	A	O	O	O	O	O	O	O	O	O	
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O	O	O	
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of reviewer

*Rori K. Craver DVM*

Date

3/5/04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 03/05/04	NAME OF FOREIGN LABORATORY Croatian Veterinary Institute
FOREIGN GOV'T AGENCY Croatian Veterinary Administration	CITY & COUNTRY Zagreb, Croatia	ADDRESS OF LABORATORY Savska c. 143 10000 Zagreb, Croatia	
NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Dr. Davorin Bazulic, Branko Sostaric, DVM		

RESIDUE	ITEM NO.	COMMENTS
		chc = chlorinated hydrocarbons abc = antibiotics op = organophosphates te = trace elements, heavy metals des = diethylstilbestrol, hormones sulf = sulfonamides iver = ivermectin clen = clenbuterol chlo = chloramphenicol car = carbadox spe = species identification Lm = <i>Listeria monocytogenes</i>
Lm	7	Because of the product exported to the US, Lm testing is not required. However, the method used is ISO 11290-1:1999 and this method has not been sent for an equivalence determination.
des	8	Urine is the tissue for testing.  BSE testing is being done with the Prionics test. An extensive plan is in force. No case of BSE has yet been recorded in Croatia.

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE  
 03/12/04

NAME OF FOREIGN LABORATORY  
 Croatian Veterinary Institute  
 Regional Laboratory at Krizevci

FOREIGN GOVT AGENCY  
 Croatian Veterinary Administration

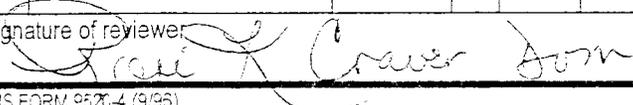
CITY & COUNTRY  
 Krizevci, Croatia

ADDRESS OF LABORATORY  
 Zakmardjeva 10  
 48260 Krizevci, Croatia

NAME OF REVIEWER  
 Rori K. Craver, DVM

NAME OF FOREIGN OFFICIAL  
 Darko Majnaric, DVM

Residue Code/Name			car	ecol	sal	abc	sulf	Lm	stap	O15 7					
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A				
	Sample Frequency	02		A	A	A	A	A	A	A	A				
	Timely Analysis	03		A	A	A	A	A	A	A	A				
	Compositing Procedure	04		O	O	O	O	O	O	O	O				
	Interpret Comp Data	05		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	EVALUATION CODE	A	A	C	A	A	C	A	C				
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A				
	Equipment Operation	09		A	A	A	A	A	A	A	A				
	Instrument Printouts	10		A	O	O	A	A	O	O	O				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O	O	A	A	O	O	O				
	Recovery Frequency	12		O	O	O	A	A	O	O	O				
	Percent Recovery	13		O	O	O	A	A	O	O	O				
	Check Sample Frequency	14		A	A	A	A	A	A	A	A				
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A	A	A	A				
	international Check Samples	17		O	O	O	O	O	O	O	O				
REVIEW	Corrected Prior Deficiencies	18	Eval. CODE	O	O	O	O	O	O	O					
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of reviewer  


Date  
 3/12/04

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 03/12/04	NAME OF FOREIGN LABORATORY Croatian Veterinary Institute Regional Laboratory at Krizevci
FOREIGN GOV'T AGENCY Croatian Veterinary Administration	CITY & COUNTRY Krizevci, Croatia		ADDRESS OF LABORATORY Zakmardijeva 10 48260 Krizevci, Croatia
NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Darko Majnaric, DVM		

RESIDUE	ITEM NO.	COMMENTS
		car = carbadox ecol = generic E. coli sal = Salmonella spp. abc = antibiotics sulf = sulfonamides Lm = Listeria monocytogenes stap = Staphylococcus aureus O157 = E. coli O157:H7
Lm	7	Because of the product exported to the US, Lm testing is not required. However, the method used is ISO 11290-1:1999 and this method has not been sent for an equivalence determination.
O157	7	Beef products are not presently eligible for export to the US. However, the method used is ISO 16654:2001 and this method has not been sent for an equivalence determination.
sal	7	Because of the product exported to the US, Salmonella testing is not required. However, the method used is HRN EN 12824 (1999) which uses 37 degrees C as opposed to 35 degrees C. This method has not been sent for an equivalence determination.

REVIEW DATE  
 03/10/04

NAME OF FOREIGN LABORATORY  
 Podravka Central Laboratory

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY  
 Private

CITY & COUNTRY  
 Koprivnica, Croatia

ADDRESS OF LABORATORY  
 Ante Starcevic 32  
 Koprivnica, Croatia

NAME OF REVIEWER  
 Rori K. Craver, DVM

NAME OF FOREIGN OFFICIAL  
 Nevenka Gasparac, Branka Gosek-Ciric

Residue Code/Name			ecol	sal	Lm	O15 7										
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A	A	A	A									
	Sample Frequency	02		A	A	A	A									
	Timely Analysis	03		A	A	A	A									
	Compositing Procedure	04		O	O	O	O									
	Interpret Comp Data	05		O	O	O	O									
Data Reporting	06	A	A	A	A											
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	C	A									
	Correct Tissue(s)	08		A	A	A	A									
	Equipment Operation	09		A	A	A	A									
	Instrument Printouts	10		O	O	O	O									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O	O	O									
	Recovery Frequency	12		O	O	O	O									
	Percent Recovery	13		O	O	O	O									
	Check Sample Frequency	14		A	A	A	A									
	All Analyst W/Check Samples	15		A	A	A	A									
	Corrective Actions	16		A	A	A	A									
International Check Samples	17	O	O	O	O											
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O									
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer  
*Rori K. Craver DVM*

Date  
 3/10/04

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 03/10/04	NAME OF FOREIGN LABORATORY Podravka Central Laboratory
FOREIGN GOV'T AGENCY Private	CITY & COUNTRY Koprivnica, Croatia		ADDRESS OF LABORATORY Ante Starcevic 32 Koprivnica, Croatia
NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Nevenka Gasparac, Branka Gosek-Ciric		

RESIDUE	ITEM NO.	COMMENTS
Lm	7	<p>ecol = generic E. coli  sal = Salmonella spp.  Lm = Listeria monocytogenes  O157 = E. coli O157:H7</p> <p>Because of the product exported to the US, Lm testing is not required. However, the method used is ISO 11290-1:1999 and this method has not been sent for an equivalence determination.</p>

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PIK Vrbovec d. d. Zagrebačka cesta 148 Vrbovec, Hrvatska	2. AUDIT DATE March 8, 2004	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY CROATIA
5. NAME OF AUDITOR(S) Rori 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	
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	X
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	X
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.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)	O	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

CROATIA - Est. 10, PIK Vrbovec d. d. March 8, 2004

38. 9 CFR §416.2(a) – Spider webs were noted in several areas high above the rails and pans of the porcine slaughter area. No slaughter was in process. No slaughter will be allowed by the Croatian state veterinarians at the establishment until the area has been cleaned and any necessary repairs have been accomplished to prevent spider entry.

44. 9 CFR §416.2(h)(2) – The soap at the hand sinks in the dressing rooms was too thick to pass through the dispensers.

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 Aurora K. Craver DVM

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danica d.o.o. Đelekovačka cesta 21 Koprivnica, Hrvatska	2. AUDIT DATE March 9, 2004	3. ESTABLISHMENT NO. 139	4. NAME OF COUNTRY CROATIA
5. NAME OF AUDITOR(S) Rori 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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
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.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)	O	54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment:

CROATIA - Est. 139, Danica d.o.o. March 9, 2004

40, 51. 9 CFR §307.2(m)(2), §416.2(c) – There was insufficient light for inspection at both the level of the viscera pans and carcass inspection below the level of the kidneys. Readings on the light meter were 42-43 foot candles. Additional lighting will be installed before the next day of slaughter.

41. 9 CFR §416.2(d) – Condensation was observed on rails in the beef processing room. Although some condensation was over product, no actual contamination was observed. Condensation was also noted in several areas of the ceiling in the same room but none was over product. Product was retained for veterinary disposition.

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

*Aurora K. Craver DVM*

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Podravka d.d. Danica 12 Koprivnica, Hrvatska	2. AUDIT DATE Mar. 10, 2004	3. ESTABLISHMENT NO. 299	4. NAME OF COUNTRY CROATIA
5. NAME OF AUDITOR(S) Rori 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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. -	
30. Corrective Actions	O	59. -	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

CROATIA Est. 299, Podravka d.d. March 10, 2004

19. 9 CFR §417.4 – Not all parts of on-going verification were present in the HACCP plan for the designated CCPs.

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

*Aurora K. Craver DVM*

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gavrilović d.o.o. Duga ulica 59 Petrinja, Hrvatska	2. AUDIT DATE Mar. 15, 2004	3. ESTABLISHMENT NO. 399	4. NAME OF COUNTRY CROATIA
5. NAME OF AUDITOR(S) Rori 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	
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.	X	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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
Part C - Economic / Wholesomeness		49. Government Staffing	
23. Labeling - Product Standards		50. Daily Inspection Coverage	
24. Labeling - Net Weights		51. Enforcement	X
25. General Labeling		52. Humane Handling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		53. Animal Identification	O
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	O
27. Written Procedures	O	55. Post Mortem Inspection	O
28. Sample Collection/Analysis	O	Part G - Other Regulatory Oversight Requirements	
29. Records	O	56. European Community Directives	O
Salmonella Performance Standards - Basic Requirements		57. Monthly Review	
30. Corrective Actions	O	58.	
31. Reassessment	O	59.	
32. Written Assurance	O		

## 60. Observation of the Establishment

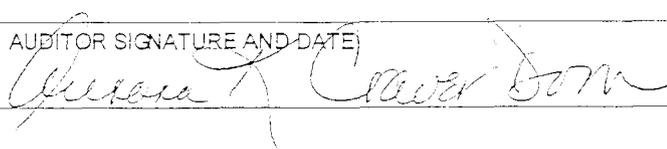
CROATIA - Est. 399, Gavrilovič d.o.o. March 15, 2004

12. 9 CFR §416.15 Some corrective action records do not include all three actions, especially preventive actions.
- 13, 51 9 CFR §416.16 No records are kept for operational sanitation.
19. 9 CFR §417.4 (a)(2) Verification is written as a separate program and does not include all three parts of verification.
20. 9 CFR §417.3 (c) There is some incomplete documentation of corrective actions on HACCP forms.

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 Aurora K. Craver DVM



REPUBLIKA HRVATSKA  
MINISTARSTVO POLJOPRIVREDE,  
ŠUMARSTVA I VODNOGA GOSPODARSTVA  
Veterinary Administration

10000 Zagreb, Ul. grada Vukovara 78, P.P. 1034  
Telefon: 61 06 111, Telefax: 61 09 200

Class: 322-01/04-/01/326  
File No.: 525-06-04-02/NG/  
Zagreb, June 23, 2004

USDA/FSIS  
Washington DC 20250  
14<sup>th</sup> & Independence Avenue, SW  
To: Sally Stratmoen, Director  
International Equivalence Staff  
Office of International Affairs

Re: Reply by the competent authority of the Republic of Croatia to the Draft  
Report of the USDA/FSIS on-site audit carried out from March 04 –  
2004 in the Republic of Croatia

Dear Dr. Stratmoen,

We are sending you a short reply to the received Draft Report related to the on-site audit carried out by the USDA/FSIS in the Republic of Croatia in the period from March 04 – 19, 2004, by Aurora K. Craver, DVM who visited us with a purpose to check up and officially verify the veterinary inspection system.

Since we have subsequently received the Report, by this letter we declare that we do not have any objections to the Draft Report from the year 2004 and as far as the deficiencies mentioned therein are concerned we have discussed them and have initiated their removal.

Now, we would like to inform you that all the deficiencies found on the day of the audit are removed in all the export establishments. Beside that, the competent authority has organised training for veterinary inspectors during the course of which the inspectors have been once again instructed in details about the procedures laid down by the Directive 5000.1, rev. 1. Also, at the training course every veterinary inspector has been given a copy of the Croatian translation the Directive 5000.1, rev.1 in order to ensure better understanding and as efficient implementation of USAD/FSIS prescribed conditions as possible.

We would like to thank you very much for all the professional cooperation extended by the Auditor A.K.Craver DVM, as well as by your competent authorities.  
Sincerely yours,

Assistant to the Minister- Director



Mate Brstilo, Dr.Sc.

C.C.: 1, Embassy of the USA, Zagreb, Tomaz Dujic, Dr.Sc.  
Agricultural Specialist - Mrs. Andrea M...