



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250



Dr. Mate Brstilo
Assistant to the Minister-Chief Executive
Veterinary Directorate
Ministry of Agriculture and Forestry
Ul. grada Vukovara 78, P.P. 1034
10000 Zagreb
Republic of Croatia

Dear Dr. Brstilo:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Croatia's meat inspection system June 18 through July 2, 2008. Comments to the draft final report from Croatia have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

by Don Carlson, Acting Director

for Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
202-205-3873
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FEB 10 2009

MEMORANDUM

TO: Quintin Gray, Minister Counselor
US Embassy, Vienna
A-1091 Wien Boltzmanngasse 16
Vienna, Austria

FROM: Manzoor Chaudry
Deputy Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR CROATIA

Dear Mr. Gray,

Please deliver the attached final audit report to Dr. Mate Brstilo, Assistant to the Minister-Chief Executive, Veterinary Directorate, Ministry of Agriculture and Forestry. Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

By Don Carter, acting Director

FD Manzoor Chaudry

cc list:

Quintin Gray, Minister Counselor, US Embassy, Vienna
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Croatia Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Croatia
FINAL AUDIT LETTER February 9, 2009

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

JUNE 18 THROUGH JULY 2, 2008

**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 Supervisory Periodic 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, Fisheries, and Rural Development
CVI	Croatian Veterinary Institute
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
<i>Lm</i>	<i>Listeria monocytogenes</i>
MAFRD	Ministry of Agriculture, Fisheries and Rural Development
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
SPS	Sanitation Performance Standards
VD	Veterinary Directorate
VID	Veterinary Inspection Directorate

1. INTRODUCTION

The audit took place in Croatia from June 18 through July 2, 2008.

An opening meeting was held on June 18, 2008, in Zagreb, Croatia with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, and 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, Fisheries, and Rural Development (MAFRD) and/or representatives from the county and local inspection offices.

2. OBJECTIVES OF THE AUDIT

This audit was a routine audit. The objectives of the audit were special emphasis on the humane handling of slaughter of livestock and 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: Headquarters of the CCA, one County inspection office, three establishment level inspection office, one government microbiology laboratory performing analytical testing on U.S.-destined product, one meat processing, and two slaughter/processing, establishments.

2.1 Comparison of the Current Audit and the Previous Audit

	6/18/2008- 7/2/2008	9/6/2007- 9/17/2007
Levels of Government Oversight Audited		
Headquarters	1	1
Central	1	1
Local Level (Establishment Level)	3	1
Laboratories Audited		
Microbiology	1	0
Residue	0	1
Establishments Audited		
Slaughter/Processing	2	0
Processing	1	1

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with officials of the CCA 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 county offices. The third part involved an on-site visit to two meat slaughter/processing establishments. The fourth part involved visits to one government laboratory, Croatian Veterinary Institute – Zagreb Laboratory for Food, which was conducting analyses of field samples for microbiological testing of food of animal origin.

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 and Sanitation Performance Standards, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Points (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 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 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, periodic 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's requirements.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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's website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The last two FSIS audits for Croatia were held in March/April 2006 and September 2007. No establishments were delisted and no Notices of Intent to Delist (NOID) were issued by the CCA during either audit. Inspection system monitoring, control records, and establishment system documents were also audited.

The following deficiencies were identified during the 2006 audit:

- In two establishments, beaded and dripping condensation was observed on overhead structures, pipes, rails in areas where exposed product was stored or in areas where employees handling exposed products were working.
- In one establishment, employees were handling product cartons, opening the cartons, and handling exposed product without sanitizing their hands or contact surfaces between these actions.
- A hydraulic hose on a product mixer was rough and worn in a section that could contact tubs of exposed product.
- In one establishment, blood, hair, and debris from the previous day's operations were observed on the floor in the slaughter area during pre-operational sanitation inspection.
- Fat and product residue were observed on a hose and spray nozzle used at the carcass evisceration station during pre-operational sanitation inspection.
- A door that opened out to the loading dock for inedible material storage did not seal sufficiently to exclude insects and vermin from entering the establishment.

The following deficiencies were identified during the 2007 audit:

- Preventive measures were not included as a part of corrective actions for SSOP deficiencies in the establishment and official inspection records.
- In the HACCP records, there were no initials or signature for one verification activity for CCP1, some temperature monitoring entries for CCP2 were missing for "Tea Pate" product, and during the pre-shipment record review it was not clear that all critical limits were met and, if appropriate, corrective actions were taken.
- In the equipment washing room, rusty metal was observed on the overhead structure at the entrance door.
- In the raw product un-packaging room, heavy condensate was observed on ceiling and overhead pipes.
- In the processing room, a metal table used for holding processing supplies had product residue buildup and meat pieces in the open end table frame structure, and a piece of plastic patch and rough welding were observed on the conveyer belt.

- In the processing room, liquid was observed dripping on the fine grinding equipment from the overhead refrigeration unit and there was product residue buildup inside an electrical switch panel cover.

These specific deficiencies were found to have been corrected by the June/July 2008 FSIS audit.

6. MAIN FINDINGS

6.1 Government Oversight

The Veterinary Directorate (VD), and Veterinary Inspection Directorate (VID) are the central government competent bodies for veterinary service in Croatia. The VD, and VID are part of the Ministry of Agriculture Fisheries and Rural Development (MAFRD). The VD, and VID are supported by, and cooperate with four 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 County Veterinary Officers at 20 County Offices and the City of Zagreb. These County Veterinary Offices directly oversee the Approved Veterinary Inspectors that are located at the local Approved Veterinary Organizations.

6.1.1 CCA Control Systems

There is a Program for Inspection Activities issued each year by the Veterinary Directorate 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 from the Veterinary Law (Official Gazette No. 41/2007). All of the Approved Veterinarians at the first level of inspection are approved directly by the MAFRD. All of the Authorized Veterinarians at the inspection level are hired by the private Veterinary Organizations acting as private limited liability companies under contract and by authorization of the MAFRD. The program for the year allows for additional inspection control as needed.

6.1.3 Assignment of Competent, Qualified Inspectors

The VD have 33 employees veterinarians, and VID have eleven employees veterinarians in the Headquarters in Zagreb, 53 veterinary inspectors in the border crossing stations, 94 county (district) veterinary inspectors and the rest of the 965 approved veterinarians are in 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 approved veterinarian is a veterinarian authorized to perform those tasks of the CCA administration which have been assigned to authorized veterinary organizations. The head of VD, at the proposal of an authorized veterinary organization, appoints approved veterinarians. The MAFRD gives the authorization to official veterinarians. There is a Food Act which also provides some of the necessary guidance which is titled Food Act (Official Gazette No. 46/2007). This Food Act 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 MAFRD 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 and laboratory personnel.
- Label approval records such as generic labels and animal raising claims.
- 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 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 of the examination of these documents.

6.3.1 Audit of County Office and Local Inspection Site

The auditor conducted a review of inspection system documents at the County office in Zagrebacka with the County Veterinary Inspector/Supervisor and also with the Veterinarian-in-Charge at three establishments visited.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of one processing establishment, and two slaughter/processing establishments. No establishment was neither delisted nor received a Notice of Intent to Delist (NOID) by Croatia inspection officials.

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

8. LABORATORY AUDITS

While the actual residue laboratory visit was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, County, and local inspection office. During these interviews, emphasis was placed on ensuring that the application of procedures and standards are equivalent to U.S. requirements. Assessment of the residue laboratory focused on sample receipt, timely analysis, analytical methodologies, recording and reporting of results.

No concerns arose as a result of these interviews.

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 government microbiology laboratory was audited:

Croatian Veterinary Institute- Zagreb Laboratory for Food Microbiology, located in Zagreb.

No concerns arose as a result of this audit.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused 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 audit of the only meat processing establishment, 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, welfare facilities, and outside premises.

9.1 SSOP

The meat processing establishment audited was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the establishment audited was found to meet the basic FSIS regulatory requirements, with following deficiencies:

- Preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the official inspection records.
- During pre-operational sanitation inspection in the cutting room, product residues were observed on the knives, on the sharpening steels, and meat and fat pieces were observed on the ham measuring device.
- During pre-operational sanitation inspection in cooling chamber number 4, heavily beaded condensate was observed dripping onto exposed carcasses.
- During the carcass wash, the water was splashing on the overhead structure and dripping back on the carcass at the final carcass wash station.

9.2 Sanitation

The enforcement of all aspects of FSIS sanitation requirements were not implemented by government inspectors in the meat processing only establishment audited.

The following deficiencies were noted:

- In the dry storage room, paper towels were stacked against the wall, which impeded inspection; also, there was condensate on the overhead ceiling above the stacked paper towels.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring 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 in the meat processing only establishment visited.

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 meat processing controls. The controls include the following areas: 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 meat processing establishments.

11.1 Humane Handling and Slaughter

No deficiencies were reported regarding humane handling or humane slaughter.

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 U.S. domestic inspection program.

The HACCP programs were reviewed during the on-site audit of the meat processing establishment. The establishment had adequately implemented the basic HACCP systems requirements.

The following deficiencies were noted for ongoing HACCP systems requirements:

- The HACCP plan indicated that in case of deviation from the critical limit of CCP 1 (fecal contamination), 10 carcasses which had passed the monitoring location of CCP 1 would be monitored, instead of re-inspection of all carcasses back to the last acceptable monitoring check.
- The hazard analysis did not indicate at which step in the slaughter process the carcasses may become contaminated by milk.

11.3 Testing for Generic *E. coli*

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

The two slaughter/processing establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing.

The following deficiency was reported.

- The sequence of swine carcass sponging for generic *E. coli* was not being followed as required (ham, belly and jowl).

11.3 Testing for *Listeria monocytogenes*

The meat processing only establishment audited was producing ready-to-eat products for export to the United States. The products presently exported to the United States are fully cooked, commercially sterile 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 included sample collection, handling and frequency, timely analysis, data

reporting, tissue matrices for analysis, analytical methodologies, recording and reporting of results.

Croatia's national residue program was being followed as written.

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*.

Some U.S. requirements were not adequately enforced in 2 of 3 establishments audited.

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

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the establishments audited.

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.

Salmonella testing was properly conducted in the slaughter establishments audited.

13.3 Species Verification

Species verification was being conducted in the establishments audited. No deficiencies were observed.

13.4 Supervisory Periodic Reviews

During this audit, it was found that at the certified establishments being audited, supervisory periodic reviews of the 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 for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

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

14. CLOSING MEETING

A closing meeting was held on July 2, 2008, with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

For Farooq Ahmad, DVM
Senior Program Auditor

by Don Carlson, DVM

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gavrilovic d.o.o. Gavrilovicev trg 1 Petrinja, Hrvatska	2. AUDIT DATE 6/24/2008	3. ESTABLISHMENT NO. 399	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Farooq Ahmad, 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	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

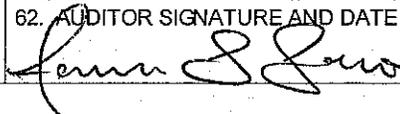
Date: 6/24/2008 Est #: 399 (Gavrilovic d.o.o. [P]) (Petrinja, Croatia)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



8/21/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION DANICA d.o.o. Delekovacka cesta 21 Koprivnica 48 000	2. AUDIT DATE June 23, 2008	3. ESTABLISHMENT NO. 139	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Farooq Ahmad, 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	X
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	X
19. Verification and validation of HACCP plan.		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	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: June 23, 2008 Est #: 139 (DANICA d.o.o. [S/P]) (Koprivnica, Croatia)

12/13/51 Preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the official inspection records. The inspection officials assured that immediate corrective actions would be taken.
[Regulatory references: 9 CFR §416.15, §416.16 and §416.17]

20/51 The HACCP plan indicated that in case of deviation from the critical limit of CCP 1 (fecal contamination), 10 carcasses which had passed the monitoring location of CCP 1 would be monitored, instead of re-inspection of all carcasses back to the last acceptable monitoring check. The inspection officials assured that immediate corrective actions would be taken.
[9 CFR §417.3 and §417.8]

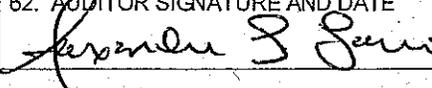
22/51 The hazard analysis did not indicate at which step in the slaughter process the carcasses may become contaminated by milk. The inspection officials assured that immediate corrective actions would be taken. [9 CFR §417.2 and §417.5]

38/46/51 In the dry storage room, paper towels were stacked against the wall, which impeded inspection; also, there was condensate on the overhead ceiling above the stacked paper towels. The inspection officials took regulatory control actions.
[9 CFR §416.1 and §416.2 (a)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 8/21/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PIK Vrbovec d. d. Zagrebacka cesta 148 Vrbovec 10 340	2. AUDIT DATE 6/26/2008	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Farooq Ahmad, 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.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	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	
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	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	X	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	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

Date: 6/26/2008 Est #: 10 (PIK Vrbovec d. d. [S/P/CS]) (Vrbovec, Croatia)

10 During pre-operational sanitation inspection in the cutting room, product residues were observed on the knives, on the sharpening steels, and meat and fat pieces were observed on the ham measuring device. Inspection official took regulatory control actions. [Regulatory references: 9 CFR §416.13, §416.15]

12/41 During pre-operational sanitation inspection in cooling chamber number 4, heavily beaded condensate was observed dripping onto exposed carcasses. Inspection official took regulatory control actions. [9 CFR §416.13, §416.15]

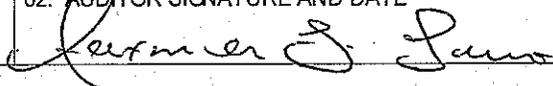
12/51 During the carcass wash the water was splashing on the overhead structure and dripping back on the carcass at the final carcass wash station. Inspection official assured immediate corrective actions. [9 CFR §416.15, §416.17]

27/28/51 The sequence of swine carcass sponging for generic *E. coli* was not being followed as required (ham, belly and jowl). The inspection official assured immediate corrective actions. [9 CFR §310.25(2)(i) and §310.25(c)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 8/21/08



REPUBLIKA HRVATSKA
MINISTARSTVO POLJOPRIVREDE,
RIBARSTVA I RURALNOG RAZVOJA

Veterinary Inspection Directorate
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Class: 322-07/08-01/5
Filing number: 525-11-08-8/TK
Zagreb, September 18, 2008.

Donald Smart, Director
USDA, FSIS, OIA, IES
Rm. 3805-S
1400 Independence Ave., SW
Washington, D.C. 20250

Subject: Reply by the competent authority of the Republic of Croatia to the draft final audit report of the USDA/FSIS inspection carried out from June 18, 2008, to July 2, 2008 in the Republic of Croatia

Dear Dr. Smart,

We are sending you a short reply to the received FSIS draft final audit report, related to the inspection carried out by the USDA/FSIS in the Republic of Croatia during the period from June 18 through July 2, 2008. In that time Dr. Farooq Ahmad visited us with a purpose of checking and officially verifying Croatia's veterinary meat inspection system.

Regarding on identified deficiencies during the USDA/FSIS audit, we report that corrective measures was initiated immediately, during the monitoring by USDA/FSIS inspector, and has been continued after the completion of the audit. Corrective action measures initiated and verified by the competent veterinary inspectorate, confirm that all deficiencies have been eliminated .

With this letter we declare, that we do not have any objections to the FSIS draft final report of an audit carried out in Republic of Croatia covering Croatia s meat inspection system, from year 2008.

We would like to thank you very much for all the instructions given to us, as well as for an open professional cooperation extended by USDA/FSIS inspector during the inspection as well as your competent authorities.

Sincerely yours,



C.C.: 1. U.S. Embassy, Thomas Jefferson 2, 10 010 Zagreb, Croatia
Foreign Agricultural Service, Agricultural Specialist- Mrs. Andrea Misir
2. Archives-here