



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
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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 has completed an on-site audit of Croatia's meat inspection system. The audit was conducted from March 22 through April 6, 2006. Comments from Croatia have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL

SEP 14 2006

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

MARCH 22 THROUGH APRIL 6, 2006

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, 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
CVI	Croatian Veterinary Institute
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
SPS	Sanitation Performance Standards
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
<i>Lm</i>	<i>Listeria monocytogenes</i>

1. INTRODUCTION

The audit took place in Croatia from March 22 through April 6, 2006.

An opening meeting was held on March 22, 2006, 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, 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, three establishment level inspection offices, two laboratories performing analytical testing on United States-destined product, two slaughter and processing establishments, and one meat processing only establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	County	1	
	Local	3	Establishment level
Residue Laboratories		1	
Microbiology Laboratories		1	
Meat Slaughter and Processing Establishments		2	
Meat Processing Establishments		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 on-site visits to three establishments: two slaughter and processing establishments and one processing only establishment. The fourth part involved visits to two government laboratories, the Croatian Veterinary Institute – Zagreb (CVI) Microbiological Laboratory, which was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species (*Salmonella*), and the CVI - Zagreb Residue and Chemistry

Laboratory which 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 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 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/Foreign_Audit_Reports/index.htm

The last two FSIS audits for Croatia were held in March 2004 and March 2005. 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 2004 audit:

- U.S. requirements had not been fully implemented and were not being adequately enforced.
- Low light intensity (42-43 foot candles) was noted at two official inspection stations.
- Operational sanitation records were not kept in one establishment.
- In one establishment, some corrective action records did not include all three corrective actions. Preventive measures were most often missing.
- In one establishment, spider webs were found above the rails and pans of the porcine slaughter line. No slaughter was in process at the time.
- 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 was too thick to pass through the dispenser.
- In one establishment, there was some incomplete documentation of corrective actions on HACCP forms. In some instances, there was no product disposition documented and in others, no preventive measures were recorded.
- In two establishments, not all parts of on-going verification were present in the HACCP plan for the designated CCPs. In some cases there was no direct observation of the monitor listed and in others there was no calibration of instrumentation listed.

The following deficiencies were identified during the 2005 audit:

- In one establishment, the stainless steel bins used for edible product in the processing room had rough welds.
- In one establishment, no waste receptacles were present at the hand wash sinks in the deboning room.
- In one establishment, equipment used in the ice production room was not stored in a sanitary manner.
- In one establishment, the ice production room was not maintained in a sanitary condition.
- In one establishment, containers of flavoring were opened in a manner that prevented resealing of packages and protection of unused ingredients.
- In two establishments required to submit samples for *Salmonella* testing, the number of samples submitted was less than the two per month required by the equivalence agreement.

- In one establishment, species verification testing was not being performed as required.

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 County Veterinary Officers at 20 County Offices and the City of Zagreb. These County Veterinary Offices directly oversee the Authorized Veterinary Inspectors that are located at the local Veterinary Stations.

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 from the Veterinary Law (Official Gazette No. 71/1997, 105/2001 and 172/2003). All of the Authorized Veterinarians above the inspection level are hired directly by the MAFVMVA. All of the Authorized Veterinarians at the inspection level are hired by the Veterinary Stations acting as private limited liability companies under contract and by authorization of the MAFVMVA. 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 940 authorized 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 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 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 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 Regional and Local Inspection Sites

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

- Vouchers and records for payment of in-plant veterinarians.
- MAFVM plan of control for County Veterinarians for the year 2006.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of three establishments, two slaughter and processing establishments and one processing only establishment. None of the establishments were delisted by Croatia. None of the establishments received a Notice of Intent to Delist (NOID) the establishment from Croatia.

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

8. LABORATORY AUDITS

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

The residue laboratory audit focused 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, international check samples, and quality assurance programs, including standards books and corrective actions.

The microbiology laboratory audit focused on the following parameters: the role of the laboratory relative to other laboratories involved in U.S. export testing; which U.S. export establishments and products were being tested; the U.S. export testing activities; the receipt of samples from all the establishments the laboratory says it services; the testing of samples for the relevant pathogens and at the relevant frequencies; the receipt of the correct type of sample; and the testing of the correct amount of product sample for the analysis. 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 above parameters were also used for the private laboratory.

The following laboratories were reviewed:

The CVI - Zagreb at Zagreb, a government laboratory, was audited for residues. The CVI – Zagreb at Zagreb, a government laboratory, was audited for microbiology. Training records for lab personnel were provided at each laboratory.

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 three establishments were found to meet the basic FSIS regulatory requirements, with no deficiencies.

9.2 Sanitation

The enforcement of all aspects of FSIS sanitation requirements was not implemented by government inspectors in the three establishments audited.

The following deficiencies were noted:

- 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.
- In one establishment, blood, hair, and debris from the previous days operations were observed on the floor in the slaughter area during pre-operational sanitation inspection.
- In the same establishment, fat and product residue were observed on a hose and spray nozzle used at the carcass evisceration station during pre-operational sanitation inspection.
- In one establishment, a door that opened out to the loading dock for inedible materials storage, did not seal sufficiently to exclude insects and vermin from entering the establishment.
- In one establishment, a hydraulic hose on a product mixer was rough and worn in a section that could contact tubs of exposed product.

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 observed.

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.

No deficiencies were observed.

11.1 Humane Handling and Slaughter

No deficiencies were observed.

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 three establishments. All establishments had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

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

Two of the three establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were 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.

11.3 Testing for *Listeria monocytogenes*

All of the three 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, 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 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 CVI - Zagreb at Zagreb, a part of the Croatian government, was audited.

The following deficiencies were noted:

- The documents presented for review did not demonstrate that the frequency of sample submission and analysis would meet the Croatian National Residue Sampling plan to the current year.
- The completion of analyses and reporting of results exceeded thirty days for many of the residue compounds, including chlorinated hydrocarbons, organophosphates, and heavy metals.
- The tissue matrix submitted for organophosphate residue determination was muscle rather than fat and no equivalence determination has been submitted to FSIS for this method.
- There was no documentation of internal quality assurance procedures being performed at this laboratory including recovery frequency, percent recovery, check sample frequency, and individual analyst check samples.

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 three 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.

No deficiencies were observed.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required. No deficiencies were observed.

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.

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 April 6, 2006, 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 Timothy B. King, DVM
Senior Program Auditor

Manzoor H. Chaudry

15. ATTACHMENTS

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

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PIK Vrbovec d.d. Zagrebacka cesta 148 Vrbovec, Hrvatska 10 340	2. AUDIT DATE 3/27/2006	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Timothy King, 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	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.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		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

Est.#: 10

City and Country: Vrbovec, Croatia

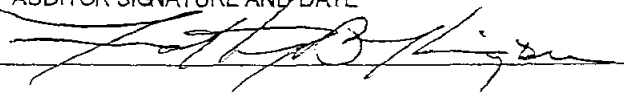
Date: 03/27/2006

- 39-51 The door from a stairwell in the processing building that opened to the loading dock for the inedible trailer had a .5 cm gap between the top of the door and its frame allowing the possible entry of insects into the processing areas. Immediate corrective action was taken by the establishment. 9 CFR 416.2(b)(3)
- 41-51 During operations, on the swine slaughter line, condensation was observed forming and dripping from the carcass rail and exposed water pipes above establishment personnel. No direct product contamination was observed but potential cross contamination by establishment employees existed. 9 CFR 416.2(d)
- 45-51 During pre-operational sanitation inspection of the swine slaughter line, in the area of the carcass evisceration station, a drop hose and spray nozzle was observed with fat, blood, and tissue residue present on it from previous days operations. 9 CFR 416.3(a)
During the same inspection, an accumulation of hair, blood, and dirt, from the previous day's slaughter, was observed on the floor under the blood collecting pan in the sticking and bleeding area. Both of these areas were controlled by the government inspector and sanitation was restored by the establishment before slaughter operations were started. No product was affected. 9 CFR 416.4(b)

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

 4/15/06

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danica d.o.o. Delekovacka cesta 21 Koprivnica, Hrvatska 48 000	2. AUDIT DATE 3/29/2006	3. ESTABLISHMENT NO. 139	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Timothy King, 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	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		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

Est.#: 139

City and Country: Koprivnica, Croatia

Date: 03/29/2006

41-51 In a carcass cooling chamber (# 102/1) and at the end of the transfer chain near the boning room heavily beaded condensation was observed on pipes, refrigeration unit drip pans, and overhead structures. Hanging carcasses were present in the cooling chamber but no carcasses were directly under the areas of condensation. Regulatory control action was initiated by the government inspector to prevent use of the carcass cooler rails. 9 CFR 416.2(d)

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

Timothy B. King 4/13/06

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gavrilovic d.o.o. Gavrilovicev trg. 1 Petrinja, Hrvatska	2. AUDIT DATE 3/31/2006	3. ESTABLISHMENT NO. 399	4. NAME OF COUNTRY Croatia
	5. NAME OF AUDITOR(S) Timothy King, 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	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	
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.		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	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

Est.#: 399

City and Country: Petrinja, Croatia

Date: 3/31/2006

39-51 One of the hydraulic hoses on a product mixer was worn and roughened in a way that could allow formation of bio-films, this worn section of the hose could also contact tubs filled with product.
9 CFR 416.3(a)

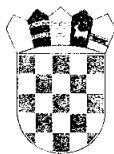
46-51 In the product transfer area employees were observed moving boxes of product from pallets to a table, opening the boxes, unwrapping the product, and pushing it across the table and through a metal detecting device without sanitizing the table surface or their hands after handling the unopened boxes. 9 CFR 416.4(a)(d)

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

Timothy B. King DVM 4/13/06



REPUBLIKA HRVATSKA
MINISTARSTVO POLJOPRIVREDE,
ŠUMARSTVA I VODNOGA GOSPODARSTVA

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

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Zagreb, July 24, 2006

Sally White, Director
USDA, FSIS, OIA, IES
Rm. 2137-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 March 22 through April 6, 2006 in the Republic of Croatia

Dear Dr. White,

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 March 22 through April 6, 2006. In that time Dr. Timothy B. King visited us with a purpose of checking and officially verifying Croatia's veterinary meat inspection system.

In our Corrective Action Plan which we sent to you on May 5th, we reported about elimination of inconsistencies based on a preliminary USDA/FSIS audit. With this letter we declare, that we do not have any objections to the FSIS draft final audit report from year 2006.

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,


Assistant to the Minister – Director
Mate Brstilo
Mate Brstilo, Ph.D

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