



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

AUG 15 2005

Dear Dr. Brstilo:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Croatia's meat inspection system March 16 through March 31, 2005. The comments from Croatia have been included in the final FSIS audit 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

Cc:

Quintin Gray, Minister Counselor, US Embassy, Vienna

Givko Gubelina, Economic Counselor, Croatia Embassy

James Dever, FAS Area Officer

Robert Macke, ITP, FAS

Amy Winton, State Department

Barbara Masters, Administrator, FSIS

Linda Swacina, Executive Director, FSIA, OIA

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Donald Smart, Director, Program Review, OPEER, FSIS

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Clark Danford, Director, IEPD, OIA, FSIS

Mary Stanley, Director, IID, OIA, FSIS

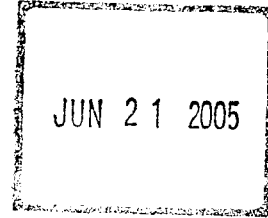
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Country File

FINAL



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

MARCH 16 THROUGH MARCH 31, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority, 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 16 through March 31, 2005.

An opening meeting was held on March 16, 2005, in Zagreb, Croatia with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of Croatia's meat inspection system.

The auditors were 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, one local Veterinary Station, three establishment level inspection offices, four 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	
	Veterinary Station	1	
	Local	3	Establishment level
Residue Laboratories		2	
Microbiology Laboratories		2	
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 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 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 three government laboratories and one private laboratory. Both the Croatian Veterinary Institute – Zagreb (CVI), Regional

Laboratory at Križevci and the Microbiological Laboratory within the Department of Quality Control of Danica Meat Industry were conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species (*Salmonella*). The CVI - Zagreb at Zagreb and CVI at the Regional Laboratory at Križevci were conducting analyses of field samples for Croatia's national residue control program.

Program effectiveness assessment determinations of Croatia's inspection system focused on evaluation of these five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (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 *Escherichia coli* (*E. coli*), (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species (*Salmonella*).

During all on-site establishment visits, the auditors evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditors 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 lead 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 January 2002 and March 2004. Two establishments were audited in 2002 (10 and 139) and four establishments were audited in 2004 (10, 139, 299, and 399). All establishments were acceptable on each audit. Inspection system monitoring, control records, and establishment system documents were also audited.

The following deficiencies were identified during the 2002 audit:

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

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.

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 920 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 auditors 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 Petrinja 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. The Veterinary Station in Petrinja was also audited. 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 2005.

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

7. ESTABLISHMENT AUDITS

The FSIS auditors 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. 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.

This was a special emphasis residue laboratory audit that 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.

Microbiology laboratory audits 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, Regional Laboratory at Križevci, also a government laboratory, was audited for residues and for microbiology. The Microbiology Laboratory within the Department of Quality Control in the Danica Meat Industry, a private company laboratory, was also audited. Training records for lab personnel were provided at each Laboratory.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focus on five areas of risk to assess Croatia's meat inspection system. The first of these risk areas that the FSIS auditors 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.

9.2 Sanitation

The following deficiencies were noted:

- In one establishment, in several processing rooms, some of the stainless steel bins used for edible product had rough welds which could allow for the formation of biofilms.
- In one establishment, no waste receptacles were present in the porcine deboning area at any of the several hand-wash sinks.
- In one establishment, the paddle used to move ice in the ice production room was not stored in a sanitary manner when not in use; the paddle was leaning against a wall.
- In one establishment, the ice production room was not maintained in a sanitary manner. Horizontal supports had dust on them and the tiles near the ice-chipping equipment had grease on them.
- In one establishment, the containers of garlic flavoring had been opened by punching a hole in the top rather than using the cap. This left the containers open for possible contamination.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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 have 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 auditors 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 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 auditors 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 and the CVI - Zagreb Regional Laboratory at Križevci, both a part of the Croatian government, were audited.

The following deficiency was noted:

- International check samples were not being conducted at the residue laboratories.

Croatia's National Residue Testing Plan for 2005 was being followed and was on schedule.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors 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.

The following deficiency was noted:

- The government microbiology laboratory had not received from either establishment the number of *Salmonella* samples in 2004 that were required by the equivalence determination.

13.3 Species Verification

Species verification was not being conducted in one of the three 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 establishment when they have a product eligible for export to the U.S.


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 31, 2005, in Zagreb, Croatia with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

 Aurora K. Craver, DVM
Senior Program Auditor



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 PIK Vrbovec d. d. Zagrebačka cesta 148 Vrbovec, Hrvatska 10 340	2. AUDIT DATE Mar. 18, 2005	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	X
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	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	
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, PIK Vrbovec d. d.
March 18, 2005
Croatia

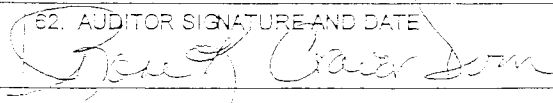
33. The total number of *Salmonella* species sponge samples (23) submitted to the CVI-Zagreb laboratory at Križevci was less than 24 as required by the equivalence agreement (a minimum of 2 samples per month).
45. In several processing rooms, some of the stainless steel bins used for edible product had rough welds which could allow for the formation of biofilms. New bins are on order and the Veterinary Service will verify their usage.
9 CFR 416.3(a)

All previous deficiencies had been corrected.

61. NAME OF AUDITOR

Roni K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 3/18/05

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 Mar. 21, 2005	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	X
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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60. Observation of the Establishment

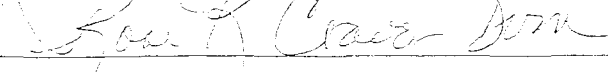
Est. 139, Danica d.o.o.
March 21, 2005
Croatia

33. The total number of *Salmonella* species sponge samples (21) submitted to the CVI-Zagreb laboratory at Križevci was less than 24 as required by the equivalence agreement (a minimum of 2 samples per month).
44. No waste receptacles were present in the porcine deboning area at any of the several hand-wash sinks. 9 CFR 416.5(a)
- All previous deficiencies had been corrected.

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 Rori K. Craver, DVM 3/21/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gavrilovič d.o.o. Duga ulica 59 Petrinja, Hrvatska	2. AUDIT DATE Mar. 24, 2005	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	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs 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	X
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	
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, Gavrilović d.o.o.
March 24, 2005
Croatia

34. Species verification testing was not being performed. 9 CFR 327.2(a)(2)(i)(F)
45. The paddle used to move ice in the ice production room was not stored in a sanitary manner when not in use; the paddle was leaning against a wall. 9 CFR 416.3(a)
46. The ice production room was not maintained in a sanitary manner. Horizontal supports had dust on them and the tiles near the ice-chipping equipment had grease on them. 9 CFR 416.4(b)

The containers of garlic flavoring had been opened by punching a hole in the top rather than using the cap. This left the containers open for possible contamination. 9 CFR 416.4(d)

All previous deficiencies had been corrected.

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver, DVM 3/24/05



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 09 201

Class: 322-01/05-/01/368
 File No.: 525-06-05-02/NG/
 Zagreb, June 13, 2005

USDA/FSIS
 Washington DC 20250
 14th & Independence Avenue, SW

To: **Sally White, Director**
 International Equivalence Staff
 Office of International Affairs
 Fax :001 202 690 4040

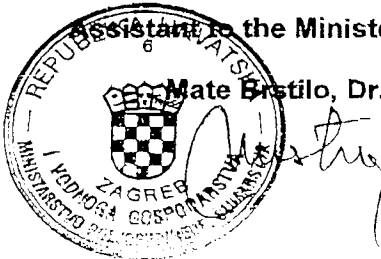
**Re: Reply by the competent authority of the Republic of Croatia
 to the Draft Report of the USDA/FSIS on-site audit carried out from
March 16 through 31, 2005 in the Republic of Croatia**

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 16 – 31, 2005, by Aurora K. Craver, DVM; Dr. Alam R. Khan, International Audit Officer. Dr. Jay Vodela, Toxicologist, OPHS 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 2005 and as far as the deficiencies mentioned therein we have discussed them and initiated their removal.

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. DVM


C.C.: Embassy of the USA, Zagreb, Tomasa Jeffersona 2
 Agricultural Specialist - Mrs. Andrea Misir