United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAR 0 4 2010

Dr. Gordan Jerbic
Uprava za veterinarske inspekcije (Directorate for Veterinary Inspection)
Address: Hotel Internacional, Miramarska 24
Republic of Croatia

Dear Dr. Gordan Jerbic:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Croatia's meat inspection system September 16 to September 29, 2009. Comments received from the government of Croatia have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

CC: List for Letters

James Dever, Minister Counselor, US Embassy, Rome
Domagoj Juričić, Economic Counselor, Croatia Embassy
Andreja Misir, Ag Specialist, American Embassy, OAA, Zagreb
David Young, FAS Area Director, Europe Region OSTA/FAS
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Country File (Croatia)

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

SEPTEMBER 16 THROUGH 29, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AV	Authorized Veterinarian
CCA	Central Competent Authority: Ministry of Agriculture, Fisheries, and Rural Development
CCP	Critical Control Point
CVI	Croatian Veterinary Institute
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
Lm	*Listeria monocytogenes*
MAFRD	Ministry of Agriculture, Fisheries and Rural Development
OV	Official Veterinarian
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
Salmonella	*Salmonella* species
SSOPs	Sanitation Standard Operating Procedure(s)
SPS	Sanitation Performance Standards
VD	Veterinary Directorate
VID	Veterinary Inspection Directorate

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Croatia from September 16 through 29, 2009. This was a routine audit. Croatia is eligible to export pork products to the United States. At the time of the audit, three establishments were eligible to export to the United States. Between January 1, 2009 and August 15, 2009, Croatia exported 97, 732 pounds of pork products to the United States and between January 1 and December 31, 2008, 230,136 pounds of pork products; there were no rejections for any food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit conducted in July 2008 resulted in no restrictions of any Croatian establishment's ability to export pork products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		09/16-09/29, 2009	06/18-07/02, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	1
	Establishment Level	3	3
Laboratories Audited			
	Microbiology	1	1
	Residue	1	0
Establishments Audited			
	Slaughter/processing Processing	2 1	2 1
	Cold Storage	0	1
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	8	5
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	1	3
	Residue Controls	0	0
	Microbiology Controls	0	0
	Inspection/Enforcement Controls	9	6

1.3 Summary Comments for the Current Audit

The results of this audit reflected an increase in the number of audit findings regarding Sanitation Standard Operating Procedures (SSOPs) and Sanitation Performance Standards (SPS), compared previous audit. Although some aspects of FSIS requirements were not enforced in all three establishments audited, the review of the government oversight of Croatia's meat inspection system at the central, regional and local (establishment) offices demonstrated that inspection system controls were in place. All

non-compliances reported during the previous audit were determined to have been addressed and corrected in all establishments involved.

2. INTRODUCTION

The audit took place in Croatia from September 16 through 29, 2009.

An opening meeting was held on September 16, 2009, 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.

3. OBJECTIVE OF THE AUDIT

This was a routine 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, one microbiology laboratory performing analytical testing on products destined for the United States, one meat-processing establishment, and two slaughter/processing establishments.

4. 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 two slaughter/processing establishments and one meat-processing establishment. The fourth part involved visits to one government-owned and -operated laboratory, the CVI - Zagreb Residue and Chemistry Laboratory, which was the reference microbiology laboratory and was also 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 SSOPs and 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 *E. coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species *(Salmonella)*. Croatia's inspection system was assessed by evaluating these five risk areas.

During the 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, 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, SSOPs, and testing for *E. coli* and *Salmonella.*

Equivalence determinations are those that have been made by FSIS for Croatia under provisions of the Sanitary/Phytosanitary Agreement. One alternative procedure has been determined by FSIS to be equivalent for Croatia: Samples for testing for *Salmonella* are collected by establishment personnel and sent to private laboratories for analysis.

5. 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.

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS 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 September 2007 and July 2008. 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 audited.

The following non-compliances were identified during the 2007 audit:

- Preventive measures were not included as a part of corrective actions for SSOP deficiencies in the some establishment and official inspection records.
- In the HACCP records, there were no initials or signature for one verification activity for one Critical Control Point (CCP), some temperature monitoring entries for one CCP were missing for "Tea Pate" product, and it was not clear in the pre-shipment

document records that all critical limits were met and, if appropriate, corrective actions were taken.

- In an equipment washing room, rusty metal was observed on an overhead structure at the entrance door.
- In a raw-product unwrapping room, heavy condensate was observed on ceilings and overhead pipes.
- In a processing room, a metal table used for holding processing supplies had a buildup product residue, meat pieces were observed in the open-ended frame of a table, and a piece of plastic patch and rough welding were observed on a conveyer belt.
- In the processing room, liquid was observed dripping on grinding equipment from an overhead refrigeration unit, and there was a product residue buildup on the inside surface of an electrical switch panel cover.

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

The following non-compliances were identified during the 2008 audit:

- 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 knives and on the sharpening steels and meat and fat pieces were observed on a ham-measuring device.
- During pre-operational sanitation inspection in a cooling chamber, heavily-beaded condensate was observed dripping onto exposed carcasses.
- Water was splashing onto overhead structures and dripping back onto the carcass at the final carcass wash station.
- In the dry storage room, paper towels were stacked against a wall, which impeded inspection; also, there was condensate on the ceiling above the stacked paper towels.
- The HACCP plan indicated that, in case of a deviation from the critical limit for absence of visible fecal contamination, only 10 carcasses which had passed the monitoring location would be monitored, instead all carcasses back to the last acceptable monitoring check.
- The hazard analysis did not indicate at which step in the slaughter process the carcasses might become contaminated by milk.
- The sequence required for the sponge-sampling of swine carcass for generic *E. coli* (ham, belly and jowl) was not being followed.

7. MAIN FINDINGS

7.1 Government Oversight

There has been a re-organization within the Ministry of Agriculture, Fisheries and Rural Development since March 2008. The Veterinary Directorate has been divided into three Directorates: a Veterinary Directorate (VD), a Veterinary Inspection Directorate (VID), and a Food Safety Directorate. The VID is responsible for the official supervision of the US-eligible establishments. The VID has 227 employees and three sectors: A Veterinary

Inspection Sector (VIS) with 159 employees, a Sector for Border Veterinary Inspection and International Trade with 62 employees, and a Department for Legal Acts and Financing of Official Controls with 4 employees. 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.

The VIS has 7 State Veterinary Offices: Bjelovar, Osijek, Rijeka, Split, Varazdin, and the headquarters office in Zagreb. These State Veterinary Offices have 65 branch offices; three of the branch offices (with headquarters in Bjelovar and Zagreb) are in charge of all US-eligible establishments. The responsibilities of the State Veterinary Inspectors include:

1. the activities of official veterinarians
2. the activities of authorized veterinarians
3. the activities of control bodies
4. performing official controls of establishments for slaughter of animals, processing, and treatment and storage of products of animal origin
5. performing official controls of establishments for residues of harmful substances in animals and products of animal origin intended for human consumption
6. performing official controls of the activities of diagnostic and analytical laboratories
7. performing official controls by collecting samples of diagnostic material for laboratory tests for the purpose of checking animal health, sanitary safety of products of animal origin, and animal feed

There was a change in the organizational structure in August 2009: The position of an Official Veterinarian (OV) was created. The OVs are responsible for overall establishment oversight and supervision of Authorized Veterinarians (AVs). AVs are responsible for the oversight of the daily operations (ante-and post-mortem inspection, SSOPs, HACCP programs, microbiology and residue testing). Both OVs and AVs are under the supervision of a State Veterinary Inspector (SVI), who reports to the Head of the Veterinary Inspection Sector.

7.1.1 CCA Control Systems

A Program for Inspection Activities is issued each year by the Veterinary Directorate with a minimum frequency proscribed for the various 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.
The inspection officials assigned to the US-eligible establishments are employed by Private Veterinary Organizations (PVOs). The PVOs are contractors of the Ministry of Agriculture, Fisheries and Rural Development for the period of 5 years.

Final authorization for the Authorized Veterinarians in US-eligible establishments comes from the Veterinary Inspection Directorate, MAFRD. All Official Veterinarians are employees of the Ministry of Agriculture, Fisheries and Rural Development.

AVs are paid by the PVOs. The PVOs collect salaries for the AVs assigned to US-eligible establishments from the MAFRD. The OVs are paid directly by the MAFRD.

7.1.2 Ultimate Control and Supervision

The OVs are responsible for overall establishment oversight and supervision of AVs, and are employees of MAFRD. The above structure is described in the Veterinary Law (Official Gazette No. 41/2007). All of the AVs at the first level of inspection are approved directly by the MAFRD. All of the AVs 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 each year allows for additional inspection control as needed.

7.1.3 Assignment of Competent, Qualified Inspectors

The VID is responsible for the official supervision of the US-eligible establishments and has 227 employees and three sectors:

1. Veterinary Inspection Sector (VIS) with 159 employees;
2. Sector for Border Veterinary Inspection and International Trade with 62 employees
3. Department for Legal Acts and Financing of Official Controls with 4 employees

The rest of the 965 Approved Veterinary Inspectors are employed in various positions in animal health; public health; meat, poultry and milk inspection, and at the various laboratory facilities.

7.1.4 Authority and Responsibility to Enforce the Laws

The AVI is a veterinarian authorized to perform those tasks of the CCA administration which have been assigned to authorized veterinary organizations. The head of the VD, at the proposal of an authorized veterinary organization, appoints Approved Veterinarians. The MAFRD grants the authorization to official veterinarians. A Food Act (Official Gazette No. 46/2007) also provides some of the necessary guidance. This Food Act brings clearer definition of the responsibilities of both veterinary and sanitary inspection in terms of official controls of foods of animal origin.

7.1.5 Adequate Administrative and Technical Support

The MAFRD has adequate administrative and technical support and has the ability to support a third party audit.

7.2 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
- Sampling and laboratory analyses for microbiology
- 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, and 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.

7.2.1 Audit of a County Office and Local Inspection Sites

The auditor conducted a review of inspection system documents at the County office in Koprivnica with the County Veterinary Inspector/Supervisor and also in the inspection offices in the three establishments audited.

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

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two slaughter/processing establishments and one processing establishment. No establishment was delisted and none received a Notice of Intent to Delist (NOID) by Croatian inspection officials.

Specific non-compliances are noted in the attached individual establishment review forms.

9. LABORATORY AUDITS

The Croatian Veterinary Institute-Zagreb Laboratory for Residue was audited, and the laboratory officials' performance was assessed regarding procedures and standards which 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 this audit.

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 U.S. 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-owned and -operated microbiology laboratory was audited:

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

No concerns arose as a result of this audit.

10. 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 audits of the three establishments, and except as noted below, Croatia's inspection system had controls in place for SSOP programs, all aspects of facilities 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, 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.

10.1 SSOP

The establishments audited were evaluated to determine if the basic FSIS regulatory requirements for SSOPs were being met according to regulatory requirements. The SSOPs were found to meet the basic FSIS regulatory requirements, with the following areas of non-compliance:

- During pre-operational sanitation inspection in one establishment, a large hole of 30 to 15 cm, completely perforating the vinyl cloth conveyor belt carrying edible product was observed. Additionally, several small cuts were observed in the second belt carrying edible product, which made it difficult to clean.
- During pre-operational sanitation inspection in one establishment, fat pieces on the product contact surface of a cutting table were observed.
- During the pre-operational sanitation inspection in one establishment, a Mortadella processing machine had two pieces of fat on the surface of a food contact area, the product processing table was observed with grease on the product contact area, and the can washing machine was observed with the remains of cleaning chemicals on the product contact area.
- Descriptions of the non-compliances were missing in the daily SSOP records of the establishment. There was an indication that corrective action was taken but what was the reason for corrective action was unknown.

10.2 Sanitation Performance Standards

The enforcement of some aspects of FSIS SPS requirements were not implemented by government inspectors. The following non-compliances were noted:

- During pre-operational sanitation inspection in one establishment, it was observed that re-usable towel, not paper towel was used at one hand washing facility.
- During pre-operational sanitation inspection in the cutting room of one establishment, product residues on the outside of a non-product contact surface of a container were observed.
- During pre-operational sanitation inspection in the cutting room of one establishment, condensate was observed on a cooling unit over a product-flow area was (product affected).
- During pre-operational sanitation inspection in one establishment, it was noted that floor tiles in the shipping area were missing or in need of repair.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These include controls 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.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was slaughter and 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.

12.1 Humane Handling and Slaughter

No deficiencies were reported regarding humane handling and slaughter.

12.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented HACCP programs. Each of these programs was evaluated according to regulatory requirements. The following non-compliance was reported:

- In one establishment, the written HACCP plan did not address point 3 and 4 of the required aspects of corrective actions to be taken in the event that critical limits are exceeded.

12.3 Testing for Generic *E. coli*

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

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

12.4 Testing for *Listeria monocytogenes*

The processing establishment 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 that are not exposed to the environment after the heat treatment. Therefore, testing for *Listeria monocytogenes* is not required by FSIS.

13. 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, and recording and reporting of results.

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

14. 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 all 3 establishments audited.

The specific non-compliances reported are noted in the attached individual establishment review forms. The SSOP, SPS and HACCP implementation aspects of controls were not adequately enforced.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in the establishments audited.

14.2 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.

14.3 Species Verification

Species verification was being conducted in the establishments audited. No non-compliance was reported.

14.4 Supervisory Periodic Reviews

Supervisory periodic reviews of the certified establishments were being performed and documented as required.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product; security of 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.

Croatia does not import any livestock or meat from other countries for use in meat products for export to the United States.

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

15. CLOSING MEETING

A closing meeting was held on September 29, 2009, 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.

Oto Urban, DVM
Senior Program Auditor

Oto Urban DVM

16. 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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
PIK Vrbovec d. d. Zagrebacka cesta 148 Vrbovec 10 340	6/26/2009	10	Croatia
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

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

10/12/51. I observed both an establishment employee and the inspector performing pre-operational sanitation inspection. I performed a pre-operational inspection after the plant and the inspector, and observed a large opening (approximately 25 cm long and 5-10 cm wide) on a conveyor belt carrying edible product; neither the establishment employee nor the inspection service had noted this non-compliance. Additionally, several small cuts were observed on the other belt, which made belt difficult to clean. The inspection official took regulatory actions and required the establishment to remove the affected areas on the conveyer belts and replace them. I reviewed SSOP records for the previous 30 days and noted that no findings regarding this non-compliance had been documented by either the establishment or the inspection officials, although daily inspection and monthly supervisory reviews were performed by the Croatian Inspection Service. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 416.13, 416.15, 416.17] **(2)**

10/51. I observed both an establishment employee and the inspector performing pre-operational sanitation inspection. I performed a pre-operational inspection after the plant and the inspector, and observed pieces of fat on the product contact surface of a cutting table; neither the establishment employee nor the inspection service had noted this non-compliance. Inspection officials ordered immediate corrective action. I reviewed SSOP records for the previous 30 days and noted that some similar findings had been documented by both the establishment and the inspection officials. [9 CFR §327.2(a)(2)(i)(D), 416.13, 416.17] **(1)**

44/51. I observed both an establishment employee and the inspector performing pre-operational sanitation inspection. I performed a pre-operational inspection after the plant and the inspector, and observed that a re-usable towel was in place for use at one hand washing facility in the processing room. Neither establishment personnel nor inspection officials had observed this non-compliance. Inspection officials ordered immediate corrective actions. I reviewed SSOP records for the previous 30 days and noted that no findings regarding this non-compliance had been documented by either the establishment or the inspection officials. [9 CFR §327.2(a)(2)(i)(D), 416.17, 416.2(h)] **(0)**

46/51. During pre-operational sanitation, in the corner of the small cutting room, the inspection official noted condensate on a cooling unit above the product-flow area. The inspection official took immediate corrective action. I reviewed SSOP records for the previous 30 days and noted that no similar findings had been documented by either the establishment or the inspection officials. [9 CFR §327.2(a)(2)(i)(D), 416.17, 416.4(a)] **(0)**

46/51. I observed both an establishment employee and the inspector performing pre-operational sanitation inspection. The inspector observed product residues on the outside of a container in the cutting room; this had not been noted by the establishment employee. The inspection official ordered immediate corrective action. I reviewed SSOP records for the previous 30 days and noted that some similar findings had been documented by both the establishment and the inspection officials. [9 CFR §327.2(a)(2)(i)(D), 416.17, 416.4(a)] **(0)**

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	Oto Urban 3-4-2010

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
DANICA d.o.o. Delekovacka cesta 21 Koprivnica 48 000	Septem. 23, 09	139	Croatia
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: September 21, 2009 Est #: 139 (DANICA d.o.o. [S/P]) (Koprivnica, Croatia)

12/13/51 Description of the non-compliance was missing in the daily SSOP records of the establishment. Establishment officials indicate that corrective action was taken but what was the reason for corrective action is unknown. The auditor has reviewed the Authorized Veterinary Inspector corrective action and found out that corrective action was required by the Inspection Service but establishment officials have not complied with this request. The inspection and establishment officials assured that immediate corrective actions would be taken. [Regulatory references: 9 CFR §416.15 (b), §416.16(a) and §416.17(b)] [Regulatory reference(s):]

20/51 The HACCP plan did not address all points of the corrective action (3, and 4). This non-compliance was not noted by the local inspection service. The inspection officials assured that immediate corrective actions would be taken [9 CFR §417.3 (a) and §417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	Oto Urban 3-4-2010

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Gavrilovic d.o.o. Gavrilovicev trg 1 Petrinja, Hrvatska	9/22/2009	399	Croatia
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 9/22/2009 Est #: 399 (Gavrilovic d.o.o. [P]) (Petrinja, Croatia)

10/51 Several areas of the processing department were observed with non-compliance during the pre-operational sanitation. The Mortadella processing machine had two pieces of fat on the surface of food contact area, a product processing table was observed with grease on the product contact area and the can washing machine was observed with the remains of cleaning compound also on the product contact area. The Official Veterinarian took proper corrective action and all non-compliant areas and equipment were cleaned before the start of operation. The auditor checked periodic supervisory reports of government inspectors and noticed that these type of non-compliances were noted by the inspection service 9 CFR 416.13 (c).

39/51 Floor tiles in the shipping area are in need to be repair. Several tiles were observed broken or partially not present. This deficiency was not reported by the inspection service. Proper corrective action was scheduled by the inspection service 9 CFR 416. 2 (b)(2).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	Oto Urban 3-4-2010