



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JUN 21

Dr. Mate Brstilo
Deputy Minister of Agriculture and Forestry
Ministry of Agriculture and Forestry
Ulica grada Vukovra 78
10000 Zagreb
Croatia

Dear Dr. Brstilo:

Enclosed is a copy of the Final report of the Food Safety and Inspection Service (FSIS) January 16-29, 2002, audit of Croatia's meat inspection system. We understand that the government of Croatia chose not to provide any comments regarding the draft final report of the same FSIS audit.

As I indicated in my March 22, 2002, letter regarding the January 16-29, 2002 audit findings, we appreciate your actions in correcting the deficiencies identified during the previous FSIS audit (December 2000). Regarding the current audit deficiencies, although we did not receive comments regarding the FSIS audit findings, we are confident that the government of Croatia has satisfactorily addressed the deficiencies and that meat exported to the United States from Croatia complies with U.S. import requirements.

If you have any questions regarding the enclosed Final report or the FSIS audit, please contact me at telephone number (202) 720-3781 or facsimile number (202) 690-4040. You may also reach me by email at sally.stratmoen@fsis.usda.gov. I may arrange a telephone conference with you in the near future to review the current audit findings and to answer any questions you may have regarding this audit.

Sincerely,

Steven A. McDermott

For Sally Stratmoen, Chief
Equivalence Section
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure

cc. Robert Curtis, Agricultural Counselor, American Embassy, Vienna
Givko Gubelina, Economic Counselor, Embassy of Croatia, Wash., DC
Andrew Burst, Area Officer, FAS
Bob Macke, FAS
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Donald Smart, Director, Review Staff, OFO
Amy Winton, State Department
Country File-Croatia (FY02 Audit)

FSIS:OPPDE:IPS:ES:S.MCDERMOTT:bw:6/20/02:690-0297:6/18/02:Croatia FY02 Audit



AUDIT REPORT FOR CROATIA

JANUARY 16 THROUGH JANUARY 29, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the Republic of Croatia's meat inspection system January 16 through January 29, 2002. Two establishments certified to export meat product to the United States were audited. Both were slaughter and processing establishments.

The last on-site audit of Croatia's inspection system was conducted in December 2000. Two establishments (10 and 139) were audited on-site. Inspection system monitoring, control records, and establishment system documents were also audited. Both establishments were acceptable. The following deficiencies were cited during the previous audit:

1. Pathogen Reduction (PR) HACCP. Following inconsistencies were noted in PR/HACCP implementation in both establishments
 - a) Sponge-sampling methods for *E. coli* testing was being used but excision method criteria was being employed for evaluation of test results.
 - b) *Listeria monocytogenes* testing requirements for ready-to-eat products were not being met.
 - c) No pre-shipment review had been done.
 - d) HACCP plans had not been reassessed as required.
 - e) There was no procedure for handling/reconditioning of dropped meat.
 - f) There appeared to be inadequate PR/HACCP training or comprehension by government officials and establishment employees.
 - a) Establishment 10
 - 1) One carcass in the cooler was observed with its nose contacting the floor. It was promptly retained and trimmed.
2. Intra-laboratory check samples for residue and microbiological analyses were inadequate.
3. Species identification testing was not being done.

All of the above deficiencies had been corrected prior to the current audit.

During October 1, 2000, to September 30, 2001, Croatia exported 278,893 pounds of cured/canned pork (ham and shoulders), cooked/canned beef, pasteurized canned hams and picnics, and a varied canned combination of product to the United States. At the U.S. port of entry there were no rejections on re-inspection.

PROTOCOL

The on-site audit was conducted in four parts. One part involved visits with the Croatian national meat inspection officials at Zagreb headquarters to discuss the oversight of programs and practices, including enforcement activities. The second part entailed on-site audits of Establishments 10 and 139 certified for export to U.S. The third part was visits to and review of records maintained at the national headquarters, at the District veterinary health control stations, and auditing of operations and documents in the Croatian Institute for Veterinary Medicine (residue and microbiological testing departments), Zagreb, and a regional laboratory located in Rijeka. The fourth part included a visit to a livestock farm to verify animal husbandry practices including proper use and monitoring/control of antibiotics, drugs, and other regulated chemicals or compounds.

Croatia's inspection program effectiveness determination focused on five areas of risk: (1) Sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs); (2) animal disease controls; (3) residue controls; (4) slaughter/processing controls, including the implementation of HACCP systems, and the *E. coli*, *Salmonella* species and *Listeria monocytogenes* testing programs, and (5) compliance enforcement controls, including the testing program for species identification.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined that establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Inspection controls were found to be in place in both establishments (10 and 139). However, inconsistencies were noted in some areas. Details of the findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in the report.

Entrance Meeting

An entrance meeting was held at the Croatian Ministry of Agriculture and Forestry, Veterinary Administration headquarters in Zagreb on December 5, 2000. The meeting was attended by: Mr. Tomislav Ledic, Director of the Ministry of Agriculture and Forestry; Dr. Mate Brstilo, Assistant to the Minister Director, Chief Veterinary Officer; Dr. Duro Majurdzic, Head of Veterinary Public Health Department (meat inspection); Dr. Nevenka Gašparac, Senior State (Federal) Veterinary Officer for Meat and Meat Product Inspection; Dr. Anđelco Gašpar, Head Veterinary

Inspection Department; Dr. Sanja Separovic, Head of the Animal Health Department; Professor Dr. Ivica Boban, National Residues Program; Dr. M. Ghias Mughal, Branch Chief, International Audit Staff, FSIS; Ms Branka Rajkovic, official interpreter; and Dr. Judd Giezentanner, International Audit Staff Officer. FSIS.

The following subjects were discussed:

1. Audit itinerary and travel arrangements.
2. SSOPs, HACCP, *E. coli*, *Salmonella*, and *Listeria monocytogenes* testing.
3. National residue control program, and a general discussion of Croatia's response to the FSIS questionnaire on enforcement.
4. Croatian policy of border and import controls.
5. Compliance enforcement.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Croatia's meat inspection system in December 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of the inspection system documents pertaining to the establishments listed for records review. The records review focused primarily on food safety hazards and included the following:

- Organizational structure of Animal Health and Veterinary Public Health Department.
- New initiatives and regulatory changes (Act, regulations, and policy) of which there were none.
- Internal audit/monthly supervisory reports.
- Food safety initiatives such as Sanitation standards and operating procedures (SSOPs), pathogen reduction (PR) for generic *E. coli* testing, *Salmonella* species, and *Listeria monocytogenes* testing, and Hazard Analysis and Critical Control Point (HACCP).
- Performance standards for sanitation, facilities, and equipment.
- Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
- Epidemiology and zoonotic status and trends in Croatia including control of products from livestock disease conditions.
- National residue monitoring and control program.
- Livestock husbandry practices, including use of drugs and chemical and feed additives.
- Compliance enforcement.

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

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Croatia to export meat products to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel. All U.S.-certified establishments are provided continuous inspection.

The Croatian Veterinary Service is vertically structured in the order - Ministry of Agriculture and Forestry's Veterinary Directorate, five State (Federal) Veterinary Institutions for clinical support, laboratory diagnosis and food control testing, and 120 groups of contracted veterinarians for veterinary health and clinical veterinary health support to the public, and 21 county/district public health and veterinary health control stations. The Veterinary Directorate administers inspection system activities through five departments:

- Animal Health Protection
- Hygiene of Products of Animal Origin and for Veterinary Public Health
- Veterinary Inspection
- Border Veterinary Inspection
- Administration

In the Republic of Croatia there are over 730 meat and poultry establishments. The Directorate employs about 2,239 veterinarians in government headquarters; laboratories, universities, private practitioners, and 672 animal health assistants, usually with 2-3 years of training assist them. The inspection system supervises activities of 296 organizations, 1,212 establishments for slaughter, food processing, animal treatment, and storage of product, 103 establishments for animal feed production, and 44 border crossing inspection.

The 21 District/County Veterinary Inspection offices employ 86 country veterinary inspectors, and 547 authorized veterinarians. They are employed in four Regional Veterinary laboratories in Krizevci, Rijeka, Split and Vinkovci, and the Poultry Center in Zagreb. These laboratories in conjunction with the Central Veterinary Diagnosis Laboratory in Zagreb are responsible for diagnostics, food hygiene, chemical and animal feed analysis activities, providing clinical assistance to the public, and conduct federally planned monitoring/sampling, and conducting compliance enforcement investigations through the sampling programs. The Central Veterinary Laboratory through the Veterinary directorate coordinates animal health diagnosis, and analysis for residues and animal feeds, and provides analytical confirmation and specialty support to 21 Counties/Districts.

The Croatian Veterinary Institute is comprised of 12 diagnostic/analytical departments: pathology, bacteriology, virology, parasitology, immunology, mastitis, foodstuffs hygiene, animal feed hygiene and feeding, chemistry, determination of residues, pharmacology, and zoo-hygiene. The Poultry Center is comprised of six departments: pathology, bacteriology, virology, mycology and mycotoxicology, animal feed, and biotechnology.

There are 44 Border Inspection points port of entry to control movement import and export of products and livestock at the Slovenia, Hungary, Yugoslavia, Bosnia and Herzegovina border crossings, seaports, airports, and the mail system.

Establishment Audits

Two establishments (Ests. 10 and 139) were certified to export meat products to the United States at the time this audit was conducted. Both establishments were visited for on-site audits and were determined to be acceptable. With the exception of deficiencies discussed in the report, the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Croatian Veterinary Institute (CVI) and its associated microbiology and residue control laboratories in Zagreb, and the Regional Veterinary Laboratory in Rijeka were visited. The CVI is a scientific-research and diagnostic institution. It manages five regional laboratories – the Veterinary Institute in Split, Rijeka, Vinkovci, Krizevci, and the Poultry Center in Zagreb. The principal mission includes animal health protection, jurisdiction over and control of domestic and international livestock movement, product of animal origin, animal feed and veterinary drugs. The research activity includes Bacteriology, Biochemistry, Residues, Virology, Chemistry (heavy metals and pesticides), FoodStuffs, Immunology, Pathology, and Marine Foods. This laboratory does *Listeria* testing for Establishment 10 that is generic with a culture differentiation for positive results. They run only intra laboratory check samples in government laboratories except for chloramphenicol. Chloramphenicol check samples are sent to the German government laboratory in Berlin as a part of their inter laboratory check sample program.

Responsible officials discussed biologics and animal drugs approval, implementation, monitoring and testing of samples for authorized biologics and medicaments, manufacturing and marketing of animal feeds, and control by District/County Animal Health and Food Control Stations. The laboratory analytical results were made available for verification.

The regional laboratory in Rijeka was staffed with competent and qualified staff. This laboratory conducts diagnoses and testing in the fields of: Cellular Pathology, Bacteriology, Parasitology, and Serology. They also conduct diagnostic programs in the Foodstuff Hygiene Department, the Chemical Department, and the Animal Feed Department. The Rijeka Laboratory also does microbiological analysis of marine samples. Bacterial analyses include *Salmonella*, *Staph aureus*, *Enterobacteriaceae*, *Clostridia* and *Listeria monocytogenes*. The laboratory conducts antibiotic screening tests and presumptive positive samples are sent to the laboratory in Zagreb for confirmation. There is no established procedure for testing the proficiency of the analysts.

The Rijeka laboratory lacked adequate personnel, equipment and facilities to carry out a vast sampling program, computerized tabulations and maintaining the record keeping instruments, and needed upgrading of some of the analytical equipment.

Establishment Operations by Establishment Number

The following operations were being conducted in U.S.-certified establishments:

Establishment 10 – pork slaughter, cooking and canning

Establishment 139 - pork slaughter, cooking and canning

SANITATION CONTROLS

Based on the on-site audits of establishments, Croatia's inspection system had controls in place for water potability records; chlorination procedures, back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest monitoring and control; temperature control; lighting; work space; dry storage areas; personal dress, employee habits, and hygiene; equipment sanitizing; and product storage.

Procedures for sanitary handling and re-conditioning of incidentally dropped meat were available in both establishment (Ests. 10 and 139) and posted in the slaughter departments.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

ANIMAL DISEASE CONTROLS

Croatia's inspection system had controls in place to ensure adequate animal identification, antemortem and postmortem inspection procedures, carcass and parts disposition, and procedures for sanitary handling of product. The auditor audited official documents and visited the following program areas to reach this conclusion.

Croatian on-going national disease control programs include vaccination against hog cholera, tuberculosis and brucellosis testing of cattle and swine, and rabies vaccination of dogs and cats.

APHIS has not declared Croatia clear of Foot and Mouth Disease. It was determined that livestock husbandry practices, and the disease control program in Croatia were effective. The auditor observed Trichina testing procedures in the diagnostic laboratory of Establishment 10, and found the procedures and records to be correct and complete.

U.S. Animal Plant and Health Inspection Service (APHIS) prohibits the use of beef product of Croatian origin in preparation of beef product intended for U.S. market. Croatia imports beef from Australia for preparation of U.S. export product, but Croatia is not producing beef products for the US market at this time. While visiting the Veterinary Institute, the auditor observed activities in the BSE diagnostic laboratory with an explanation of procedures. *Bovine spongiform encephalopathy* (BSE) has not been recorded in Croatia.

Animal Identification

Identification (ear tagging/marketing) of cattle, swine, sheep, goats, and canines is mandatory. Identification ear tags are issued by and the records maintained by Center for Reproduction in Livestock Breeding of Croatia.

Croatia has an effective and traceable livestock identification system.

RESIDUE CONTROLS

Croatia's national residue testing plan for FY 2000 was being followed and was on schedule. The Croatian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures, storage and use of chemicals.

The auditor visited a private livestock farm located in Zagreb County, and discussed husbandry and animal health practices with responsible County Veterinary officials. The observations and records review indicated that sufficient controls existed for inventories and authorized acquisition/use of veterinary drugs and supplemental compounds/feed additives, and withdrawal time before slaughtering.

The auditors visited the Croatian Veterinary Institute (CVI) in Zagreb, and audited residues and microbiological analytical results. CVI is comprised of laboratories for analyses of trace elements, pesticides, and veterinary drugs. All FSIS required compounds including carbadox and clenbuterol were being tested.

The auditor determined that Croatia had an effective residue control program and met U.S. requirements.

SLAUGHTER/PROCESSING CONTROLS

The Croatian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem inspection procedures; postmortem disposition; restricted product control; pre-boning trim, boneless meat inspection; ingredient identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty inspection and filling procedures; container closure examination; post-processing handling; processing defect action-plant; and processing control-inspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP program was found to meet the basic FSIS regulatory requirements. However, the following implementation problems were noted:

1. In both establishments, critical limit observations were being recorded as “OK” with a check mark, instead of recording the actual values, as required by FSIS regulations.
2. In both establishments, verification and validation were not clearly delineated.

Testing for generic *E. coli*

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

Establishments 10 and 139 were required to meet basic FSIS regulatory requirements for *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Croatian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The Croatian inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be

in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* species

Both establishments (10 and 139) were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Croatia has adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures:

1. SAMPLE COLLECTOR. Establishments take samples

- Croatia has a clearly written sampling plan with instructions for sample collection and processing that will be universally followed. This plan is outlined in documents titled “*Salmonella* Testing Plan: No. 10 and *Salmonella* Testing Plan No. 139”.
- Croatia has a means of ensuring that establishment sample collection activities and laboratory performance are acceptable. Samples are taken under direct supervision of the government veterinary inspector. The laboratories are under the supervision of the government inspection service. Confirmation testing by official government laboratories is undertaken twice each month. Test results are provided directly to the government veterinary inspector at the establishment.
- Croatia uses test results to monitor establishment performance over time.
- Croatia takes immediate action any time an establishment fails to meet a *Salmonella* performance standard.

The *Salmonella* testing programs were found to meet all of the regulatory requirements

Testing for *Listeria monocytogenes*

The Bacteriology Laboratory at the Croatian Veterinary Institute routinely performed *Listeria monocytogenes* monitoring of the fresh beef matrices (brain, kidney, liver, spleen and muscle), pork fresh matrices (brain, kidneys, livers, muscle, lungs and lymph nodes), and ready-to-eat canned product. The Veterinary Directorate determined the frequency of sampling by official inspectors, and action for violation.

Species Verification-Testing

At the time of this audit, Croatia was not exempt from species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements. Both establishments deboned and processed only pork products at this time.

Monthly Reviews

Responsible State/Federal Senior Veterinary Officers conducted U.S.-certified establishment reviews during periods of time when product was being produced for the U.S market. The supervisory Country Veterinary Officers also performed in-depth establishment audits from time to time. Additionally, in each establishment, the responsible State/Federal Senior Veterinary Officer had conducted four (4) reviews during the previous year and the County/District Veterinary Officers had conducted four (4) reviews.

Enforcement Activities

Each county's field staff officers provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs administration to the livestock and use in feed stuffs, monitor rendering facilities, and investigate violations of residue and other regulatory requirement. Violations are reported to police for legal action, and fines. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated. It was stated that actions are taken when laws are transgressed.

Exit Meeting

An exit meeting was conducted in Zagreb on January 29, 2002 and was attended by Drs. Mate Brstilo, Duro Majurdzic, Anelco Gašpar, Nevenka Gašparac, M. Ghias Mughal, Judd Giezantanner, and Ms. Branka Rajkovic (professional interpreter).

The following topics were discussed:

1. HACCP: pre-shipment reviews, documenting actual critical limit values, verification and validation activities.
2. Monthly supervisory visits.
3. Check sample frequencies.

CONCLUSION

The inspection system of Croatia was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Two establishments were audited and both were acceptable. However, inconsistencies in PR/HACCP plans and their implementation existed, which were being addressed by the inspection service. Responsible personnel had undergone formal HACCP training. It was stated that species identification analysis, branding ink, and re-conditioning of incidentally contaminated product had been corrected.

The national animal health and residue control programs were effective and met U.S. requirements.

Croatia has an extensive network of regulatory compliance enforcement systems at local, county and national level. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Judd Giezentanner
International Audit Staff Officer

(signed)Dr. Judd Giezentanner

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for generic *E. coli* testing
- D. Data collection instrument for *Salmonella* species testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (*no comments received*)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1. Written program addressed	2. Pre-op sanitation addressed	3. Operational sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible individual identified	7. Documentation done daily	8. Dated and signed
10	√	√	√	√	√	√	√	√
139	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1.Flow diagram	2.Hazard analysis done	3. All hazards identified	4. Use and users included	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Corrective actions described	9. Plan validated	10. Adeq. Verific. Proc.	11. Adequacy of documentation.	12. Dated and signed
10	√	√	√	√	√	√	*no	√	√	*no	√	√
139	√	√	√	√	√	√	*no	√	√	*no	√	√

* Basic HACCP requirements were met but HACCP was not properly implemented.

Data collection instruments for *E. coli* testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

Est. No.	*1. Written procedure	2. Sample collector designated	3. Sampling location given	4. Predominant spp. sampled	5. Sampling at required frequency	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
10	√	√	√	√	√	√	√	√	√	√
139	√	√	√	√	√	√	√	√	√	√

Data Collection instruments for *Salmonella* spp. Testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. No.	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper production	7. Violative Est. stop operations
10	√	√	√	√	√	√
139	√	√	√	√	√	√

FOREIGN COUNTRY LABORATORY REVIEW

1/21/02

Croatia Veterinary Institute

FOREIGN GOV'T AGENCY

CITY & COUNTRY
 Zagreb, Croatia

ADDRESS OF LABORATORY
 Zagreb, Croatia

NAME OF REVIEWER

Dr. Judd Giezantanner

NAME OF FOREIGN OFFICIAL

Dr. Iavorin Bazulic

Residue Code/Name			Sul	Chl	Clen	Org	Chlo	Diox	Anti	Hor	203				
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A	A			
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A			
	Timely Analyses	03		A	A	A	A	A	A	A	A	A			
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O			
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O			
	Data Reporting	06	A	A	A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A				
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A				
	Equipment Operation	09	A	A	A	A	A	A	A	A	A				
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A				
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A				
	Percent Recovery	13	A	A	A	A	A	A	A	A	A				
	Check Sample Frequency	14	C	C	C	C	C	C	C	C	C				
	All analyst w/Check Samples	15	C	C	C	C	C	C	C	C	C				
	Corrective Actions	16	A	A	A	A	A	A	A	A	A				
	International Check Samples	17	C	C	C	C	C	C	C	C	C				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A				
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 1/21/02	NAME OF FOREIGN LABORATORY Croatia Veterinary Institute
FOREIGN GOV'T AGENCY		CITY & COUNTRY Zagreb, Croatia	ADDRESS OF LABORATORY Zagreb, Croatia
NAME OF REVIEWER Dr. Judd Giezentanner		NAME OF FOREIGN OFFICIAL Dr. Iavorin Bazulic	

RESIDUE CODES	ITEM NO.	COMMENTS
All except 203	14/17	Interlaboratory check sample was not performed except for chloramphenicol.
	15	The interlaboratory check samples were not properly analyzed by supervisor.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY

CITY & COUNTRY
 Rijeka, Croatia

ADDRESS OF LABORATORY
 Rijeka, Croatia

NAME OF REVIEWER

Dr. Judd Giezentanner

NAME OF FOREIGN OFFICIAL

Dr. S. Perkovic

NO U.S. SAMPLES PROCESSED AT THIS LABORATORY

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

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 1/23/02	NAME OF FOREIGN LABORATORY Veterinary Institute Rijeka
FOREIGN GOV'T AGENCY		CITY & COUNTRY Rijeka, Croatia	ADDRESS OF LABORATORY Rijeka, Croatia
NAME OF REVIEWER Dr. Judd Giezantanner		NAME OF FOREIGN OFFICIAL Dr. S. Perkovic	
		NO U.S. SAMPLES PROCESSED AT THIS LABORATORY	

RESIDUE CODES	ITEM NO.	COMMENTS
	14/17	Interlaboratory check sample was not performed except for chloramphenicol.
	15	The interlaboratory check samples were not properly analyzed by supervisor.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY
FOREIGN PLANT REVIEW FORM		1/17/02	Est. 10 - Vrbovec, Croatia		Vrbovec
					COUNTRY Croatia
NAME OF REVIEWER Dr. Judd Giezantner		NAME OF FOREIGN OFFICIAL Drs. Nevenka Gasparac, Duro Majurdzic		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	1/17/02	Est. 10 - Vrbovec, Croatia	Vrbovec
			COUNTRY
			Croatia
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION	
Dr. Judd Giezentanner	Drs. Nevenka Gasparac, Duro Majurdzic	<input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

82 - Basic HACCP requirements had been met. However, HACCP was not fully implemented.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY	
FOREIGN PLANT REVIEW FORM		1/18/02	Est. 139 - Podravica Danica		Koprovnic	
				COUNTRY	Croatia	
NAME OF REVIEWER Dr. Judd Giezantner		NAME OF FOREIGN OFFICIAL Drs. Nevenka Gasparac, Duro Majurdzic		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable		
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply						
1. CONTAMINATION CONTROL		Cross contamination prevention		28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing		29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage		30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning		31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation		32 A	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM			Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program		33 A	Processing schedules	61 A
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Outside premises	24 A	4. PROCESSED PRODUCT CONTROL			"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim		51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection		52 A	HACCP	82 N
Personal hygiene practices	26 A	Ingredients identification		53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients		54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	1/18/02	Est. 139 - Podravica Danica	Koprovnica
			COUNTRY
			Croatia
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION	
Dr. Judd Giezantner	Drs. Nevenka Gasparac, Duro Majurdzic	<input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

82 - Basic HACCP requirements had been met. However, HACCP was not fully implemented.

Country Response Not Received