



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 23 2004

12/2/04

Dr. Tibor Balint
Chief Veterinary Officer
Ministry of Agriculture and Regional Development
Animal Health and Food Control Department
H-1860
Budapest 55
Hungary

Dear Dr. Balint:

The Food Safety and Inspection Service has completed an enforcement audit of Hungary's meat inspection system. The audit was conducted April 14 through April 23, 2004. No comments were received from the government of Hungary. Enclosed is a copy of the final audit report.

If you have any questions about the audit report, you can reach me by telephone at 202-720-3187, by facsimile at 202-690-4040, or electronic mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL

AUG 18 2004

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

APRIL 14 through APRIL 23, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AHFCD	Animal Health and Food Control Department
AHFCS	Animal Health and Food Control Station
CAP	Corrective Action Plan
CCA	Central Competent Authority [Animal Health and Food Control Department, Ministry of Agriculture and Regional Development]
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
MARD	Ministry of Agriculture and Regional Development
NFII	National Food Investigation Institute
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The audit took place in Hungary from April 14 through April 23, 2004.

An opening meeting was held on April 14, 2004, in Budapest, Hungary, with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objectives and scope of the audit and confirmed the itineraries of the auditors.

Each auditor was accompanied during the entire audit by representatives from the CCA, the County Animal Health and Food Control Station, and the National Food Investigation Institute (NFII).

2. OBJECTIVES OF THE AUDIT

This audit was an enforcement audit. There were two objectives of the audit. The first objective was to determine if Hungary had implemented its March 2004 corrective action plan. The second objective 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 objectives, the following sites were visited: the headquarters offices of the CCA and NFII, two County Animal Health and Food Control Station offices, and two establishments that were certified to export product to the United States.

Competent Authority Visits			Comments
Competent Authority	Central	2	
	County	2	Supervise Certified Establishments
Meat Slaughter/Processing Establishments		2	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with headquarters and county officials to determine if Hungary had implemented its March 2004 Corrective Action Plan (CAP) and 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 and county offices. The third part involved on-site visits to two slaughter/processing establishments.

Program effectiveness determinations of Hungary's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard

Analysis and Critical Control Points (HACCP) programs and testing programs for generic *Escherichia (E. coli)*, (4) residue controls, and (5) enforcement controls, including testing programs for *Salmonella*. Hungary's inspection system was assessed by evaluating these five risk areas.

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 Hungary 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 the headquarters of the CCA and the County Offices would be audited against Hungary's Corrective Action Plan (CAP), which was submitted to FSIS in March 2004. The CAP was developed by Hungary to address deficiencies in its meat inspection that led to the January 2004 suspension of Hungary from eligibility to export meat products to the United States.

Basic elements of the CAP included: 1) establishing an internal audit system by the CCA; 2) providing for additional supervision of certified establishments by the CCA; 3) verification by the CCA of corrective actions taken by establishments in response to deficiencies noted by the in-plant inspection personnel and/or noted during monthly supervisory reviews; 4) development of a new and comprehensive compliance checklist for use in conducting monthly supervisory reviews; and 5) delivery of specific training activities to inspection personnel and establishment personnel.

In addition, the lead auditor explained that Hungary's meat inspection system would also be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Hungary. 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, species verification, and the requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for Hungary under provisions of the Sanitary/Phytosanitary Agreement. There has been an equivalence determination, for Hungary, that generic *E. coli* samples can be analyzed in government laboratories.

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 PR/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/oppde/far.

Summary of October 2003 Audit Findings

Government Oversight

- Weaknesses were observed in two establishments of inconsistent or non-uniform implementation of US requirements.
- Weaknesses were observed in two establishments of inadequate supervision and control over official activities and certified establishments.
- There was inadequate knowledge of PR/HACCP programs by inspectors in two of the seven establishments.
- There were incidents of inadequate enforcement of FSIS requirements in two of seven establishments.
- Several monthly supervisory review reports did not include a documented review of HACCP, SSOP, and the testing programs for generic *E. coli* and *Salmonella*.

Sanitation Controls

- Inadequate maintenance of on-going requirements in two of seven establishments.
- Inadequate control of insects in three of seven establishments.
- Inadequate operational sanitation in two of seven establishments.

Slaughter/Processing Controls

- All verification frequencies were identical and instrument calibrations were too infrequent in one of seven establishments.
- Several critical control points had multiple critical limits in one establishment.
- Inadequate implementation of generic *E. coli* testing procedures in one of six slaughter establishments. Use of excision criteria to evaluate sponge results.

Enforcement Controls

- There was no apparent documentation of verification activities conducted by the inspection service.

During the April 2004 audit, all of the above deficiencies were found to be corrected.

6. MAIN FINDINGS

6.1 Government Oversight

Hungary's Animal Health and Food Control Department (AHFCD) is the CCA for Hungary's meat inspection system and the AHFCD has the ultimate control over the production of food products derived from animals. The Director of the AHFCD is accountable to the Ministry of Agriculture and Regional Development (MARD) at the national headquarters in Budapest, Hungary. The direct supervision and enforcement of FSIS requirements within Hungary's meat inspection system is provided by the individual County Animal Health and Food Control Stations (County Station) within the AHFCD. County Station Directors report directly to the Director of the AHFCD.

The NFII is an advisory arm of the AHFCD. One of its main functions is to carry out on-site audits of establishments that export meat products to the United States, the European Union, and other third countries. The NFII performs audits of these establishments twice each year with a focus on how the exporting establishments meet the importing countries' inspection requirements. In addition, the NFII assists the AHFCD by performing investigations involving food products in the areas of fraud, contamination, labeling and similar concerns.

There are twenty County Offices that have control over the meat establishments within their jurisdiction. Two of these counties are responsible for the two (one each) U.S. certified establishments that were audited.

The County Station performs the monthly supervisory visits to certified establishments. To strengthen monthly reviews of certified establishments, the AHFCD revised its current audit checklist. The revised checklist was modeled after the FSIS audit checklist and includes all of the areas related to the PR/HACCP requirements. The reviewer from the County Office, an establishment representative, and the veterinarian in charge at the establishment sign the review. Completed monthly supervisory reviews are now forwarded to the NFII for information and action.

6.1.1 Ultimate Control and Supervision

Hungary's March 2004 CAP provided for the establishment of an internal audit system to verify that certified establishments continue to meet all FSIS inspection requirements and to provide a thorough process for the review and approval of establishments that wish to become certified. This internal audit function is vested in the AHFCD and consists of

personnel from the CCA, the NFII, and other personnel directly involved with the inspection of food animals. The primary function of this newly established internal audit team is to conduct on-site audits of all establishments proposed for certification for export to the United States. In addition, team members will carry out special supervisory reviews of all certified establishments at least two times per year. The focus during the reviews of the certified establishments will be on the implementation of FSIS' PR/HACCP requirements. Of particular importance is that the team will place special emphasis on verifying how deficiencies, noted during monthly reviews or during a NFII audit, were resolved and how the inspection service is verifying the performance of the establishments in general.

6.1.2 Assignment of Competent, Qualified Inspectors

In March 2004, the AHFCD in conjunction with the NFII contracted with a private firm to provide extensive training of inspectors, inspectors in charge, County Food Hygienists, and certain CCA headquarters personnel in FSIS' PR/HACCP requirements. This training also included specific information on how the inspection service at all levels could verify and document that deficiencies noted at establishments have been corrected.

The auditors found that the training was conducted as provided for in Hungary's CAP. In addition, the training activities were found to be effective as evidenced by the fact that the FSIS auditors found no deficiencies in the two audited establishments.

6.1.3 Authority and Responsibility to Enforce the Laws

The authority and responsibility of enforcing applicable laws and regulations are vested in the AHFCD and this authority and responsibility are delegated to the County Stations for certified export establishments. The County Station delegates this authority and responsibility to the veterinarians in charge of certified establishments.

6.1.4 Adequate Administrative and Technical Support

The AHFCD has adequate administrative and technical ability to enable it to carry out its responsibilities.

6.2 Headquarters Audit

The auditors conducted a review of inspection system documents at headquarters, at two County Stations, and two establishment inspection offices. 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 inspection personnel.
- Label approval records such as generic labels.

- New laws and implementation documents such as regulations, notices, directives and guidelines.
- 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 examples of criminal prosecution.

No concerns arose as a result the examination of these documents at headquarters and at the other locations.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of two establishments. Both were slaughter and processing establishments. No establishment was delisted by Hungary and no establishment received a Notice of Intent to Delist. In addition, no deficiencies were found in either of the audited establishments.

8. MICROBIOLOGY LABORATORY AUDITS

No microbiology laboratories were audited.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess Hungary'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, Hungary'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, Hungary's inspection system had controls in place for water potability records, back-siphonage prevention, separation of operations, temperature control, workspace, 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.

No deficiencies were noted.

9.2 Sanitation

Each establishment was evaluated to determine if FSIS regulatory requirements for sanitation were met, according to the criteria employed in the United States domestic inspection program.

No deficiencies were noted.

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, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product.

No deficiencies were noted.

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; humane handling and humane slaughter; 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. No deficiencies were found in the controls listed above.

The controls also include the implementation of HACCP systems in all establishments and the 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 two establishments. Both establishments had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

Hungary has adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent different requirement. Hungary uses government laboratories to test for generic *E. coli*.

Both 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.

11.4 Testing for *Listeria monocytogenes*

Neither of the establishments audited was producing ready-to-eat products for export to the United States. Therefore, these establishments are not required to reassess their HACCP plans for *Listeria monocytogenes* and are not subject to FSIS' additional testing requirements for *Listeria monocytogenes*.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors would normally review was Residue Controls. However, during this audit, no residue laboratories were reviewed.

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 both establishments.

13.2 Testing for *Salmonella*

Hungary has adopted the FSIS requirements for testing for *Salmonella*. Both of the slaughter establishments 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.

- Testing for *Salmonella* was properly conducted in both establishments.

13.3 Species Verification

Species verification was properly conducted in both establishments.

13.4 Monthly Reviews

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 for the importation of only eligible livestock from other countries, i.e., only livestock from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

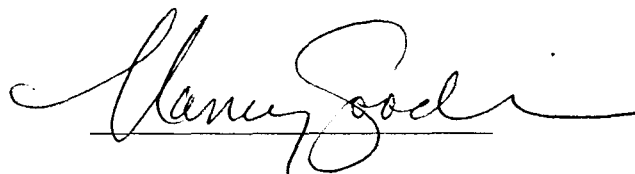
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on April 23, 2004 in Budapest, Hungary, with the CCA. At this meeting, the preliminary audit findings were presented to inspection officials.

The CCA understood and accepted the findings.

Nancy Goodwin
Lead Auditor

A handwritten signature in cursive script, appearing to read "Nancy Goodwin", written over a horizontal line.

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Pápai Hús Rt. (Pápai Meat Co.) H-8500 Pápa, Kisfaludy ut. 2.	2. AUDIT DATE 04-15-04	3. ESTABLISHMENT NO. 6	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Rori K. 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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
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

Hungary, Continuation Est.6
15 April 2004

All previous deficiencies were checked and were found corrected.

61. NAME OF AUDITOR
Rori K Craver DVM

62. AUDITOR SIGNATURE AND DATE

Rori K Craver DVM 4/15/04

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Kapuvári Hús Rt. 9330 Kapuvár Cseresznye sor 21	2. AUDIT DATE 19 April 2004	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY Hungary
	5. NAME OF AUDITOR(S) Rori K. 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		O
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		O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan.			41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
18. Monitoring of HACCP plan.			46. Sanitary Operations		
19. Verification and validation of HACCP plan.			47. Employee Hygiene		
20. Corrective action written in HACCP plan.			48. Condemned Product Control		
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards		O	51. Enforcement		
24. Labeling - Net Weights		O	52. Humane Handling		
25. General Labeling		O	53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		O	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

Hungary, Continuation Est.10
19 April 2004

All previous deficiencies were checked and were found corrected.

61. NAME OF AUDITOR
Rori K Craver DVM

62. AUDITOR SIGNATURE AND DATE

Rori K Craver DVM 4/19/04

Country Response Not Received