

Food Safety and Inspection Service Washington, D.C. 20250

Dr. Miklos Suth
Chief Veterinary Officer
Ministry of Agriculture and Regional Development
Animal Health and Food Control Department
Kossuth ter 11
H-1055 Budapest
Hungary

NOV 2 9 2007

Dear Dr. Suth:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Hungary's meat inspection system May 22 to June 1, 2007. Comments received from the government of Hungary 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 (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart Director

International Audit Staff

Office of International Affairs

Enclosure

FINAL NOV 2 1 2007

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

MAY 22 THROUGH JUNE 1, 2007

Food Safety and Inspection Service United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CAO County Agricultural Office

CCA Central Competent Authority, Food Chain Safety, Animal and

Plant Health Department

E. coli Escherichia coli

FCSAPHD Food Chain Safety, Animal and Plant Health Department, Central

Competent Authority

FSIS Food Safety and Inspection Service

FSO Food Safety Office

MARD Ministry of Agriculture and Rural Development

NAT Hungarian National Accreditation Body

PR/HACCP Pathogen Reduction / Hazard Analysis and Critical Control Point

Systems

SPS Sanitation Performance Standards

Salmonella Salmonella species

SSOP Sanitation Standard Operating Procedures

VEA European Community/United States Veterinary Equivalence

Agreement

1. INTRODUCTION

The audit took place in Hungary from May 22 through June 1, 2007.

An opening meeting was held on May 22, 2007, in Budapest, Hungary, with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Hungary's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Food Chain Safety, Animal and Plant Health Department (FCSAPHD), County Agricultural Office (CAO), and/or the Food Safety Office (FSA).

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate Hungary's meat inspection system and 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, the Veszprem CAO, the National and Central Reference Laboratory for residue and microbiology in Budapest, and two swine slaughter and processing establishments that were certified to produce and export meat products to the United States.

Competent Authority Visits			Comments
Competent Authority	Central	1	Budapest
	County	i	Veszprem
Laboratories		1	Central Laboratory
Meat Slaughter/Processing Establishments		2	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with headquarters and the Veszprem CAO 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 CAO. The third part involved the audit of two swine slaughter and processing establishments. The fourth part involved visits to one government laboratory involved in applicable residue and microbiological testing.

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, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and testing programs for generic *E. coli*, (4) residuc controls, and (5) enforcement controls, including testing programs for *Salmonella* species. Hungary's inspection system was assessed by evaluating these five risk areas.

During establishment audits, 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 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 auditor explained that Hungary's meat inspection system would be audited against three standards: (1) EC Directives found to be equivalent per EU/US Veterinary Equivalence Agreement, (2) FSIS regulatory requirements, and (3) any equivalence determinations made for Hungary. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory reviews 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* species.

Equivalence determinations are those that have been made by FSIS for Hungary under provisions of the Sanitary/Phytosanitary Agreement. One equivalence determination has been made for Hungary: Samples for generic *E. coli* may 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 Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action of B-agonists"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address: http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

During the April 2004 FSIS audit of Hungary's inspection system, no deficiencies were reported.

The October 2005 FSIS audit of Hungary's inspection system identified one deficiency in the residue laboratory:

• The laboratory was holding samples for chloramphenicol testing because the ELISA screening kits were not available at the time of the audit. The holding time exceeded the three week turnaround time limit required by the laboratory program.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Hungary's legislation.

6.2 Government Oversight

The Food Chain Safety, Animal and Plant Health Department (FCSAPHD), a public administration body under the Ministry of Agriculture and Regional Development (MARD), is the Central Competent Authority (CCA). The Chief Veterinary Officer (CVO) is appointed by the Minister of Agriculture. The CVO is the most senior-level official for international affairs of the veterinary and food inspection activities. The Deputy President (DP) of the Central Agricultural Office (MgSzH) is in charge of FCSAPHD. The FCSAPHD is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced.

6.2.1 CCA Control Systems

Hungary's meat inspection system is organized in three levels: Central, county, and food safety offices.

The first level is the FCSAPHD, Located in the Central Agricultural Office in Budapest, which consists of one audit division and six directorates as follows:

- 1) Directorate for Food and Feed Safety
- 2) Directorate of Animal Health and Welfare
- 3) Directorate of Veterinary Medical Products
- 4) Directorate of Animal Health Diagnostics
- 5) Directorate for Plant, Soil, and Agricultural Environmental Protection
- 6) Directorate for Wine Grading

The Directorate for Food and Feed Safety (DFFS) is divided into four departments as follows:

- 1) Department for Food Safety and Food Hygiene
- 2) Department for Food Distribution Safety
- 3) Department for Coordination of Regional Laboratories
- 4) Department for Feed Safety and Feed Quality Control

The Department for Food Safety and Food Hygiene (DFSFH) is responsible for:

- Oversight of the approved establishments for export to the third countries, including the approval and supervision of certified establishments for export to the USA
- Testing the hygienic suitability of equipment used in the food industry
- Supervision of the County Agricultural Offices or County Competent Authorities in relation to the activities of approved establishments
- Training of the official veterinarians and auxiliaries

The second level encompasses 19 County Agricultural Offices (CAO) that have control over the meat-processing establishments within their jurisdiction. Two of these counties (Csongrad and Veszprem) contain the U.S. certified establishments. Each CAO has a Director for Food Chain Safety and Animal Health who has overall responsibility in the county. There is also a Food Hygiene Specialist (FHS) in each county who performs the required periodic supervisory reviews of the establishments certified for U.S. export.

The Food Safety Offices (FSO) located in each of the U.S. certified establishments form the third level. Each office has an Official Veterinarian-in-Charge (OVIC) who is in charge of inspection activities in the establishment and receives direction from the CAO. The OVIC has direct supervision over all other inspection personnel assigned to the certified establishment, including associate veterinary officers and non-veterinary inspection (meat inspectors) personnel.

6.2.2 Ultimate Control and Supervision

The FCSAPHD of MARD has ultimate control over the slaughtering of livestock and production of food products derived from animals.

The CAO and the OVIC oversee the maintenance of eligibility to export to the United States. These supervisors have the authority, under the Hungary's regulations, to enforce the necessary requirements to export to another country. Their duties also include initiating investigations into failure on the part of an establishment to meet the standards of the importing country and to delist those establishments that fail in this requirement.

The OVIC in certified establishments performs the daily supervision of establishment activities. The OVIC reports directly to the FHS who performs the periodic supervisory reviews. In addition to the periodic supervisory reviews, the CCA usually performs semi-annual audits of the U.S.-certified establishments if significant non-compliances are identified either by periodic supervisory reviews or by FSIS auditors.

All inspection personnel assigned to the establishments certified to export meat to the United States are full-time government employees receiving no remuneration from either industry groups or establishment personnel.

6.2.3 Assignment of Competent, Qualified Inspectors

Each CAO is responsible for the selection, hiring, and training of inspection personnel within their jurisdiction. Veterinarians receive specialized training related to food hygiene during their veterinary education. They also gain additional knowledge and experience through periodic MARD and CAO training sessions. The meat inspectors are technical school graduates. They only perform post-mortem-related inspection activities. Each FHS and OVIC who attends MARD training sessions is expected to pass on this training to the other veterinarians in his/her county, including the other official veterinarians and meat inspectors in exporting establishments.

The OVIC has the authority to stop the establishment's production operations any time the wholesomeness and/or safety of the product is jeopardized. He/she reports directly to the FHS and consults with him/her regarding all decisions involving enforcement activities. The decision as to whether the establishment is failing to meet the U.S. import requirements and the recommendation that it should be delisted is a combined effort of the OVIC, FHS, and county director, and may also include headquarters officials.

6.2.4 Authority and Responsibility to Enforce the Laws

The FCSAPHD has the legal authority and the responsibility to enforce all FSIS requirements. The OVIC and other qualified in-plant inspection personnel are authorized to enforce European Commission (EC) legislation and U.S. import requirements. The CAO, with the assistance of its legal department and headquarters office, has the legal authority to suspend and/or delist the U.S. certified establishments to prevent the export of unwholesome products to the United States.

6.2.5 Adequate Administrative and Technical Support

The CCA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate Hungary's meat inspection system.

Administration, development, coordination, and the formation of rules and regulations take place in the headquarters of the MARD in Budapest, Hungary.

6.3 Headquarters and County Agricultural Office Audit

The auditor conducted a review of inspection system documents at the headquarters of the FCSAPHD/MARD located in Budapest. The auditor also interviewed inspection officials at the CAO located in Veszprem County for the purpose of determining the level of government oversight, supervisory structure, and to review records pertinent to one of the U.S. certified establishment. The records review focused primarily on food safety hazards and included the following:

- Government oversight documents, including organizational structure
- Periodic supervisory visits
- Training programs and personnel records of training
- Requirements for employment and payment records of inspection personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Assignment of inspectors, staffing, and inspection coverage of the U.S. certified establishment
- Inspection records and enforcement actions such as withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States
- Organization of the country's laboratory system
- Microbiology and residue sampling and laboratory analyses
- Export product inspection and control including export certificates
- Sanitation, slaughter and processing inspection procedures and standards
- Control of inedible and condemned materials
- Funding of Hungary's inspection program
- The food security/defense system

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

7. ESTABLISHMENT AUDITS

The FSIS auditor reviewed two swine slaughter and processing establishments. Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

The Department of Coordination for Regional Laboratories in Budapest supervises one National Central Laboratory and five regional laboratories. The National Central Laboratory consists of the following reference laboratories:

- 1) Central Microbiology Laboratory
- 2) Central Residue/Toxicology Laboratory
- 3) Central Analytical laboratory

- 4) Central Radio-Analytical Laboratory
- 5) Central Feed Investigation Laboratory

The Central Microbiology and Residue Laboratories, both located in Budapest, were audited.

The Central Microbiology Laboratory conducts analyzes of field samples for the presence of *Listeria monocytogenes* on ready-to-eat (RTE) products for export to the United States. Regional and/or private laboratories analyze samples for generic *E. coli* and *Salmonella* species.

The Central Residue/Toxicology Laboratory conducts analyses of field samples for Hungary's national residue program.

Both laboratories were ISO 17025-certified by the Hungarian Accreditation Body (NAT). No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess Hungary'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 establishments, 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 light, plumbing and sewage, water potability records, chlorination procedures, back-siphonage prevention, dressing rooms/lavatories, separation of operations, temperature control, workspace, ventilation, ante-mortem facilities, condemned product control, welfare facilities, and outside premises.

9.1 Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in both establishments were found to meet the basic FSIS regulatory requirements.

9.2 EC Directive 64/433

In both establishments, the provisions of EC Directive 64/433 were effectively implemented.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Hungary'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.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: Ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls for cured, dried, and cooked products. The controls also include the implementation of HACCP systems and a testing program for generic *E. coli* in this establishment.

11.1 Humane Handling and Humane 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 program was reviewed during the audit of both establishments. Both establishments had adequately implemented the HACCP requirements, except as noted below:

• In one establishment, the written HACCP plan did not include all four parts of the corrective actions to be followed in response to a deviation from the critical limit.

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 alternative procedure:

• Government laboratories perform generic E. coli testing.

Both establishments 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 slaughter establishments.

11.4 Testing for Listeria monocytogenes

Both establishments were producing ready-to-eat products for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur. No deficiencies were observed.

11.5 EC Directive 64/433

In both establishments, the provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The Central Residue/Toxicology Laboratory in Budapest is the reference laboratory for residues. It conducts analyses of field samples for the Hungary's national residue program. No deficiencies were noted.

12.1 EC Directive 96/22

In the National Central Laboratory for Residues, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Food Investigating Institute for Residues, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species. No deficiencies were observed.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in both establishments. However, in one establishment, some of the cooking/cooling operations associated with the production of

U.S. eligible fully-cooked ham were conducted outside of the official shift and without inspection supervision.

13.2 Testing for Salmonella species

Hungary has adopted the FSIS requirements for testing for *Salmonella* species. Both slaughter establishments were required to meet the basic FSIS regulatory requirements for testing for *Salmonella* species and was evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for Salmonella species was properly conducted in both establishments.

13.3 Species Verification

Species verification was being conducted as required.

13.4 Periodic Supervisory Reviews

Periodic supervisory reviews 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 from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties 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 June 1, 2007 in Budapest, Hungary, with the CCA. At this meeting, the preliminary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Nader Memarian
Senior Program Auditor

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15. ATTACHMENTS

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

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4 NAME OF COUNTRY		
Papai Hus Zrt. F.A.	5/24/2007	6	Hungary		
8500 Papa Hus Rt.	5. NAME OF AUDIT	OR(S)	6. TYPE OF AUDIT		
Papa Nader		rian TMM			
<u> </u>	1	lemarian, DVM X ON-SITE AUDIT DOC			
Place an X in the Audit Results block to in	dicate noncomp) .	
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		1	rt D - Continued onomic Sampling	Audit Results	
7. Written SSOP		33. Scheduled Sample	+		
8. Records documenting implementation.		34. Species Testing			
Signed and dated SSOP, by on-site or overall authority.		35. Residue			
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E -			
10. Implementation of SSOP's, including monitoring of implementation.		36. Export			
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import			
 Conective action when the SSOPs have faled to prevent direct product contamination or adulteration. 		38. Establishment Grounds			
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			
 Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective a 	ctions.	42. Plumbing and Sewage			
 Records documenting implementation and monitoring of the HACCP plan. 	9	43. Water Supply			
The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories 45. Equipment and Utensils			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations		-	
18. Monitoring of HACCP plan.					
19. Verification and validation of HACCP plan.		47. Employee Hygiene			
20. Corrective action, written in HACCP plan.		48. Condemned Product Co	introi		
21. Ressessed adequacy of the HACCP plan.		Part F - Inspection Requirements			
22. Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ		49. Government Staffing			
Part C - Economic / Wholesomeness		50. Daily Inspection Covera	ge	x	
23. Labeling - Product Standards		51. Enforcement			
24 Labeling - Net Weights		52. Humane Handling			
25. General Labeling					
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/M	oisture)	53. Animal Identification			
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection			
27. Written Procedures		55. Post Mortem Inspection			
28. Sample Collection/Analysis			LA Control Design		
29. Records		Part G - Other Regu	latory Oversight Requirements		
Salmonella Performance Standards - Basic Requ	lirements	56. European Community Di	rectives		
3D. Corrective Actions		57. Monthly Review			
31. Reassessment		58.			
32 Written Assurance		59,			

60. Observation of the Establishment

Date: 5/24/2007 Est #: 6 (Papai Hus Zrt. F.A. [S/P/CS]) (Papa, Hungary)

50. Some of the cooking/cooling operations associated with the production of U.S. eligible fully-cooked ham were conducted outside of the official shift and without inspection supervision. [Regulatory reference: 9CFR 327 (a)(2)(i)(D)]

The auditor was assured by the inspection officials that immediate actions will be taken.

61. NAME OF AUDITOR

Nader Memarian. DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION	2. AUDIT D	ATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY		
Pick Szeged Rt.	05/29/2	007	7	Hungary		
		F AUDITOR(S) Memarian, DVM		6. TYPE OF AUDIT		
				ON-SITE AUDIT X DOCUMEN		
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Place an X in the Audit Results block to Part A - Sanitation Standard Operating Procedure		,		ents. Use O if not applicable.	1	
Basic Requirements		Audit Results	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)			Part E - Other Requirements			
Ongoing Requirements 10. Implementation of SSOP's, including monitoring of implementation.			36. Export			
Maintenance and evaluation of the effectiveness of SSOP's.			37. Import			
Corrective action when the SSOPs have falled to prevent direct product confamination or adulteration.			38. Establishment Grounds and Pest Control			
13 Daily records document item 10, 11 and 12 above.			39. Establishment Construc	tion/Maintenance		
Part B - Hazard Analysis and Critical Control			40. Light			
Point (HACCP) Systems - Basic Requirement: 14. Developed and implemented a written HACCP plan.	<u>s</u>		41. Ventilation		ļ	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective	e actions.	х	42. Plumbing and Sewage			
16. Records documenting implementation and monitoring of HACCP plan.			43. Water Supply		ļ +	
17 The HACCP plan is signed and dated by the responsible			44. Dressing Rooms/Lavatories			
establishment individual. Hazard Analysis and Critical Control Point			45. Equipment and Utensils		<u> </u>	
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations			
18. Monitoring of HACCP plan.			47. Employee Hygiene			
19. Verification and validation of HACCP plan.			48. Condemned Product Co	ontrol		
20. Corrective action written in HACCP plan.			Part F - Inspection Requirements			
21. Reassessed adequacy of the HACCP plan.					! !	
 Records documenting: the written HACCP plan, monitor critical control points, dates and times of specific event 	ring of the occurrences.		49. Government Staffing			
Part C - Economic / Wholesomeness			50. Daily Inspection Covera	ge		
23 Labeling - Product Standards			51. Enforcement		X	
24. Labeling - Net Weights			52. Humane Handling			
25. General Labeling		 			-	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins	s/Maisture)		53. Animal Identification		ļ	
Part D - Sampling Generic E. coll Testing			54. Ante Mortem Inspection		ļ	
27. Written Procedures			55. Post Mortem Inspection			
28. Sample Collection/Analysis			Part G. Other Part	latory Oversight Requirements		
29. Records			- an O - Other Regu	natory orthogramments		
Salmonella Performance Standards - Basic Re	equirements		56. European Community D	rectives		
30. Corrective Actions			57. Monthly Review			
31. Reassessment			58.			
32. Written Assurance			59.			

60. Observation of the Establishment

Date: 05/29/2007 Est #: 7 (Pick Szeged Rt. [S/P/CS]) (Szeged, Hungary)

The written HACCP plan did not include all four parts of the corrective actions to be followed in response to any deviation from a critical limit at a critical control point. [Regulatory reference: 9CFR 417.2 (c) (5)]

The auditor was assured by the inspection officials and establishment personnel that immediate actions will be taken.

61. NAME OF AUDITOR
Nader Memarian. DVM

62. AUDITOR SIGNATURE AND DATE



Embassy of the Republic of Hungary Washington, D.C.

3910 Shoemaker Street, N.W. Washington, D.C. 20008 Telephone: (202) 362-6730/7 Telefax: (202) 966-8135, (202) 686-6412

To:

Dr. Donald Smart

Director USDA/FSIS

Fax. No.:

(402) 344-5169

Date:

November 6, 2007

Ref.: From:

Attila Tóth

Agricultural Attaché

Number of pages:

1+2

Dear Mr. Smart,

Please find enclosed the letter of Dr. Miklós Süth on the measures taken by the Hungarian Food Inspection Service to eliminate the deficiencies found during the audit conducted in Hungary from May 22 through June 1, 2007.

Sinecerely yours,

Attila Tóth

Agricultural Attaché



ANIMAL AND PLANT HEALTH

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/2007

Donald Smart,

October 16, 2007.

Director
United States Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
International Audit Staff
Office of International Affairs
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Dear Mr. Smart,

Thank you very much for the Draft Final Report of the Audit conducted in Hungary from May 22 through June 1, 2007.

I would like to provide you with information on the measures taken by the Hungarian Food Inspection Service to eliminate the following deficiencies found during the audit:

1. Deficiency at establishment HU 6:

Some of the cooking/cooling operations associated with the production of U.S. eligible fully-cooked ham were conducted outside of the official shift and without inspection supervision. The auditor was assured by the inspection officials that immediate action will be taken.

Corrective measure:

The inspection service has reorganized its service to ensure that all operations associated with the production of U.S. eligible fully-cooked ham have been covered by official inspection supervision.

2. Deficiency at establishment HU 7:

The written HACCP plan did not include all four parts of the corrective actions to be followed in response to any deviation from a critical limit at a critical control point. The auditor was assured by the inspection officials and establishment personnel that immediate actions will be taken.

Corrective measure:

The written HACCP plan has been amended in a way that it contains all the four parts of the corrective actions to be followed in response to any deviation from a critical limit at a critical control point. (All the four parts of the corrective action will be implemented even if just one carcass is contaminated to comply with the zero tolerance for visual fecal contamination). The corrective measure carried out by the establishment was verified by the inspection service.

Sincerely,

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