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

SEP 19 2002

Dr. Antal Nemeth
Head of Department
Department of Veterinary and Food Hygiene
Ministry of Agriculture and Regional Development
H-1860 Budapest V.
Kossuth L. ter 11
Hungary

Dear Dr. Antal Nemeth:

The Food Safety and Inspection Service conducted an on-site audit of Hungary's meat inspection system from February 12, 2002 through February 28, 2002. Enclosed is a copy of the final audit report dated August 5, 2002. Comments by Hungary on the draft final audit report have been included as Attachment "G" of the final audit report.

FSIS has carefully reviewed the assurances provided by Hungary at the Exit Conference in Budapest on February 28, 2002 and the comments contained in your May 30, 2002 response to the draft final audit report. We appreciate your commitment to correct all of the deficiencies found during the audit.

If you have any questions relative to the recent audit or this letter, or need additional information, please feel free to contact me at your convenience. My telephone number is (202) 720-3781, my fax number is (202) 690-4040, and my email address is sally.stratmoen@fsis.usda.gov .

Sincerely,

Sally Stratmoen

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

Enclosure

cc:

Zsolt Horvath. Ag Counselor, Embassy of the Republic of Hungary, WashDC
Robert Curtis, Counselor, FAS, U.S. Embassy, Vienne
Ferenc Nemes, Ag Specialist, FAS, U.S. Embassy, Budapest
Andrew Burst, Area Officer, FAS
Linda Swacina, Associate Administrator, FSIS
Maritza Colon-Pullano, SAIFS, OPPDE
John Prucha, ADA, OPPDE, FSIS
Amy Winton, State Department
Donald Smart, Director, Review Staff
Karen Stuck, Director, IPS, FSIS
Sally Stratmoen, Chief, ES, IPS
Richard F. Brown, ES, IPS, FSIS
Country File (FY 2002 Audit)

United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR HUNGARY

FEBRUARY 12 THROUGH FEBRUARY 28, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Hungary's meat inspection system February 12 through February 28, 2002. All seven establishments certified to export meat product to the United States were audited. Six of these were slaughter and processing establishments; one was processing only.

The last audit of Hungary's inspection system was conducted in November 2000. Six establishments were audited (Ests. 5, 6, 7, 10, 24, and 62). The auditor found significant problems in one establishment (Est. 5) that was then designated as marginal/re-review at the next audit. Major concerns reported at that time:

1. In Establishments 5, 10, 24 and 62, loose plastic strands were observed in plastic product containers.
2. There was no sanitary procedures in place to re-condition incidentally dropped meat in all establishments.
3. Establishment 5 did not identify product contact equipment to be monitored during pre-operational sanitation. Effectiveness of sanitation standards operating procedures (SSOPs) was not monitored by official inspectors.
4. *Listeria monocytogenes* as hazard likely to occur in ready-to-eat (RTE) products was not considered in Hazard Analysis Critical Control Plan (HACCP) in all establishments and there was no official policy/requirements for *Listeria* positive samples.
5. Species identification monitoring was not being done in Ests.5 and 24, and on-going species verification testing program was not documented.
6. In Establishment 5, inspection coverage was not provided during the second/night shift.
7. Other concerns included inadequate denaturing/decharacterization of inedible and condemned product.

The auditor verified that all of the above deficiencies had been corrected and all establishments operate only one shift according to Government of Hungary officials.

At the time of this audit, Hungary was eligible to export processed pork and beef products to the United States (U.S.).

During calendar year 2001, Hungarian establishments exported 4,215,865 pounds of cured pork, and pasteurized canned hams and picnics to the U.S. There was no rejection of products at the port of entry inspection during this period.

PROTOCOL

The on-site review was conducted in three parts. One part involved visits with Hungarian national meat inspection officials at Budapest headquarters to discuss oversight programs and practices, including enforcement activities. The second part entailed on-site audits of seven establishments certified for export to U.S. The third part was visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence microbiological contamination with *Salmonella.*

Hungary's program effectiveness was assessed by evaluating 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 Hazard Analysis and Critical Control Point (HACCP) systems, and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all 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 if 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

Effective inspection controls were found to be in place in all seven establishments audited (Ests. 5, 6, 7, 10, 24, 62, and 147) except as noted later in this report. Details of audit findings, including compliance with HACCP, SSOP, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

The last audit of the Hungary's meat inspection system was conducted in November 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected.

Entrance Meeting

On February 12, 2002, an entrance meeting was held at the Hungary's Ministry of Agriculture, Department of Animal Health and Food Control headquarters, and was attended by Dr. Antal Nemeth, Chief Veterinary Officer, Dr. Barnabas Sas Executive Director, National Food Investigation Institute, Budapest, Dr. Imre Rayda, Deputy Director, National Food Investigating Institute, Dr. Sándor Tili, Head Export Department, Dr. Veronica Oláh, Senior Veterinary

Officer, National Food Investigation Institute, and FSIS auditor Dr. Suresh P. Singh, and Mr. F. Nemes, FAS/US Embassy. Topics of discussions included the following:

1. Audit itinerary and travel arrangements.
2. Use of nutritional or geographic claim labels.
3. SSOPs, HACCP, *Escherichia coli (E. coli)*, *Salmonella*, and *Listeria monocytogenes* testing.
4. National residue control program.
5. FSIS policy on 'listing and delisting' of establishments.
6. Compliance enforcement.

Hungary's inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in November 2000.

Headquarters Audit

There had been no organizational changes in Hungary's meat inspection systems. Some of the key officials include:

Dr. Antal Nemeth - Chief Veterinary Officer (CVO)
Dr. Laura Herpay - Deputy CVO
Dr. Ágnes Horváth - Head of Department of Food Control
Dr. Barnabas Sas - Executive Director, National Food Investigation Institute

To gain an accurate overview of the effectiveness of inspection controls, the FSIS auditor 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. requirements. 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 site audit. The records review was conducted at the establishments and at the headquarters. The records review focused primarily on food safety hazards and included the following:

1. Organizational structure of Animal Health and Food Control Department.
2. New initiatives and regulatory changes (Act, regulations, and policy).
3. Internal review reports and monthly supervisory reports.
4. 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).
5. Performance standards for sanitation, facilities, and equipment including water potability and insect and rodent control, etc.
6. Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
7. Label approval records.
8. Epidemiology and zoonotic trends in Hungary including control of products from livestock disease conditions.

9. National residue control program.
10. Enforcement records.

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

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Hungary to export meat product 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.

In Hungary, there is an Animal Health and Food Control Station (Department) in each of 20 counties, and three veterinary institutes: Veterinary Diagnostic Central, National Food Investigating, and Veterinary Biologics, Drugs and Animal Foodstuffs. The Animal Health and Food Control Department, comprising of about 80 headquarters employees in Budapest, is managed by Dr. Antal Nemeth, Chief Veterinary Officer. Dr. Ágnes Horváth, Head of Department of Food Control, manages the national food/meat inspection programs in 20 counties. District Veterinary Directors in each of the 20 Stations supervise Animal Health and Food Control activities.

Each of the 20 county governments, in addition to the meat inspection, operate a laboratory staffed with technicians and professionals – chemists, veterinarians, agricultural engineers, veterinary and food inspectors. These laboratories provide support for animal health, food safety, pathological, microbiological and antibiotic, and animal feed testing.

The Central Veterinary Diagnostic Institute in Budapest coordinates animal health diagnostic and the residues control activities, and provides analytical confirmation and specialty support to 20 county laboratories.

Establishment Audits

Seven establishments (Ests. 5, 6, 7, 10, 24, 62, and 147) were certified to export meat products to the United States. All were visited for on-site audits. With the exceptions described in this report, generally 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 audit, 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 laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The National Food Investigation Institute Laboratory in Budapest was audited on February 26, 2002. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and print outs, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

Hungary's microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the National Food Investigation Institute Laboratory in Budapest was audited. The laboratory was well equipped and staffed with competent and qualified staff. It performs monitoring for microorganisms such as *E. coli*, *Salmonella* species, total plate counts, etc., food and meat products, food additives, animal feed stuffs and supplements, chlorinated hydrocarbons, trace elements, aflotoxins, mycotoxins, and microbiological and physico-chemical analysis of water.

Establishment Operations by Establishment Number

The following operations were being conducted in the seven establishments:
Establishment 5 – Cattle and swine slaughter, cutting, boning, curing/drying/smoking product.
Establishment 6 – Cattle and swine slaughter, cut up, boning, curing/drying/smoking, non-shelf stable product canning, and edible rendering.
Establishment 7 – Swine slaughter, cut up, boning, curing/drying/smoking, and edible rendering.
Establishment 10 – Swine slaughter, cut up, boning, curing/drying, smoking, and non-shelf stable product.
Establishment 24 – Cattle and swine slaughter, cut up, and boning.
Establishment 62 – Swine slaughter cutup, boning, curing/drying/smoking, and non-shelf stable product canning.
Establishment 147-Swine Boning, cutting, curing and smoking.

SANITATION CONTROLS

Based on the on-site audits of establishments, Hungary'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, habits, and hygiene; equipment sanitizing; and product storage.

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.

Cross-Contamination

- In Establishment. 5, there was no warm water supply in locker room because of mechanical problem and windows in locker area were not shut tight and there was potential for insects and flies.
- In Establishment 24, knife sanitizers in boning and cutting room were not maintained at 82 Centigrade temperature and cross contamination was observed on finished carcasses ready to enter in blast freezer due to dirty plastic flaps touching each carcass.
- In Establishment 62, condensation in carcass cooler was dripping, however not on carcasses; plastic containers in boning and cutting rooms were not identified for edible and inedible products.

ANIMAL DISEASE CONTROLS

Hungary'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.

There were reported to have been no outbreaks of animal diseases with public heath significance since the previous U.S. audit.

RESIDUE CONTROLS

Hungary's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Hungarian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Hungarian 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; 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. were 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 instruments used accompanies this report (Attachment B).

The HACCP program was found to meet basic FSIS regulatory requirements.

Testing for generic *E. coli*

Hungary has adopted the FSIS regulatory requirements for *E. coli* testing with the exception of the following equivalent different requirements:

1. LABORATORIES. Government laboratories.

    - The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.

    - Results of analyses including all permanently recorded data and summaries are reported promptly to the establishment.

Ests. 5, 6, 7, 10, 24, and 62 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 Hungarian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The Hungarian inspection system controls (control of restricted products 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 taking and documentation of corrective action under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (only from eligible countries and certified establishments within those countries), and the importation of only eligible meat 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

Six of the establishments audited (Ests. 5, 6, 7, 10, 24, and 62) were required to meet the basic FSIS regulatory requirements for *Salmonella* species 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).

Hungary has adopted the FSIS regulatory requirements for *Salmonella* testing.

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

The inspection service collected samples. In the case of a positive result, product is identified, re-called if available, and confiscated for further action. Future shipments are withheld subject to laboratory analyses clearance. Investigation is conducted to determine root-cause(s) of product adulteration.

Testing for *Listeria monocytogenes*

One sample was collected each month from ready to eat products and one sample from each export shipment of all ready-to-eat products. The *Listeria* adulteration and positive result from sampling of paprika salami at the port of entry in the United States in the month of January from Establishment 7 was discussed at the exit meeting. GOH officials assured that corrective actions will be taken and investigation will be done and will be reported to International policy at Washington.

Species Verification Testing

At the time of this audit, Hungary was not exempt from species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the Hungarian equivalent of Area Supervisors. All were veterinarians with at least 10 years of experience.

The internal review program was applied to all exporting establishments. Internal review visits were announced in advance and were conducted at least once monthly. The records of audited establishments were kept in the inspection offices of individual establishments, and copies were also kept in county office, and were routinely maintained on file for a minimum of 2 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify

for eligibility to be reinstated, a team with Head, Food Inspection, of National Food Investigation Institute is empowered to conduct in- depth review, and results are reported to Chief Veterinary Officer of Hungarian Government for evaluation. They formulate a plan for corrective action and preventive measures.

Enforcement Activities

Each county Station's field Veterinary Staff Officers are authorized to 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. Violators could be fined up to Fr 1,000,000. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated.

Exit Meeting

An exit meeting was conducted in Budapest on February 28, 2002. The Hungarian participants were, Dr. Ágnes Horváth; Head Food Control Department; Dr. Imre Rayda, Head National Food Investigating Institute, Dr. Sándor Tili, Head Export Department, Dr. Veronica Oláh, Senior Veterinary Officer, National Food Investigation Institute, and Dr. Suresh P. Singh, International Audit Staff Officer, TSC-FSIS-USDA.
The following topics were discussed:

1. Observations and findings in Establishments 5, 24 and 62 were discussed as reported in the cross-contamination section of this report. Hungarian officials took immediate corrective action during the review of each establishment.
2. Inspection service would evaluate and investigate for *Listeria monocytogenes* in Establishment 7 as the letter from International Policy in Washington requested.
3. Official guidelines would be issued on how to deal with situations when positive cases of *Listeria* were recorded.
4. Mechanical Deboning (319.5) requirements were discussed as requested by Hungarian Officials.

CONCLUSION

The inspection system of Hungary was found to have effective controls to ensure that products destined for export to the United States were produced under conditions equivalent to those that FSIS requires in domestic establishments. Seven establishments were audited and all were acceptable. The deficiencies encountered during on-site establishment audits were adequately and immediately addressed to the auditor's satisfaction.

Suresh P. Singh, DVM, Ph.D. (Signed)*Suresh P. Singh, DVM, Ph.D.*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audits Forms.
F. Individual Foreign Establishment Audit Forms.
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

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.Documenta-tion done daily	8. Dated and signed
5	√	√	√	√	√	√	√	√
6	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√

Attachment B

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 that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. 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.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. 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.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. No	1.Flow diagram	2.Hazard analysis done	3. All hazards identi-fied	4. Use and users included.	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Correc-tive actions described	9. Plan validated	10. Adeq. Verific. Proc.	11. Adeq. Docum.	12. dated and Signed
5	√	√	√	√	√	√	√	√	√	√	√	√
6	√	√	√	√	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data collection instrument for Generic *E. coli* Testing

Each establishment (except Est. 147) was evaluated to determine if the basic FSIS regulatory requirements for generic E. coli testing 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 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.Predomi-nant 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
5	√	√	√	√	√	√	√	√	√	
6	√	√	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection instrument for *Salmonella* testing

Each slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the 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
5	√	√	NA	√	√	√
6	√	√	NA	√	√	√
7	√	√	NA	√	√	√
10	√	√	NA	√	√	√
24	√	√	NA	√	√	√
24	√	√	NA	√	√	√
62	√	√	NA	√	√	√

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
02-26-02	National Food Investigation Institute

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
MINISTRY OF AGRICULTURE	Budapest, Hungary	H-1095

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr.S.P.Singh	Dr. Lorena Kovacsies

	Residue Code/Name ▶			80	100	111	200	203	400	500	900	S	L	SL
	REVIEW ITEMS	ITEM #												
SAMPLING PROCEDURES	Sample Handling	01	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	A	A
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17		O	O	O	O	O	O	O	O	O	O	O
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A	A	A	A	A	A	A
OTHER REVIEW		19	EVAL. CODE											
		20												

SIGNATURE OF REVIEWER

DATE

Designed on FormFlow Softwa

Attachment F

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
02-13-2002	05, Gyulai Huskombinat	Gyulai
		COUNTRY: Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr.S.P.Singh	Dr.Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ 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					
(a) BASIC ESTABLISHMENT FACILITIES		Cross contamination prevention	28 A	Formulations	55 A
		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 M	(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	6. 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	SSOP	A
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	COMMENTS MADE ON REVERSE	

FSIS FORM 9520-2 (12/01) REPLACES FSIS FORM 9520-2 (11/90) WHICH MAY BE USED UNTIL EXHAUSTED Designed on PerFORM PRO Software by Datrina

Attachment G

USDA FSIS Washington, D.C. 20250

Subject: written comments for draft final audit report.

30. 05. 2002. Budapest

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

Dear Dr. Sally Stratmoen,

Thank you for sending U.S. draft final audit report referring FSIS on-site audit beetween 13.02.2002 – 01. 03. 2002. in Hungary.

In the report of dr. Surresh P. Singh are written only such a deficiencies which were determined at the plant on the spot and were discussed later on at exit meeting.

I appreciate that dr. Singh in this new audit report determined that on privious auditation the concerns had been addressed were corrected, and the seven establishments certified for export were visited for on-site audits, with exeptions, show good hygienic standard acceptable products processing. For the deficiencies which were found during this audit, and were discussed on final meeting, corrective actions were taken immidiatedy or within short time limit.

The effectiveness of the establishments was controlled by competent county veterinary stations on the following way:

- In plant 5 there was no warm water supply in hand washing facilities in the changing rooms because of mechanical problem. In the same changing room a window was not shut tight and had no mosquito-net. The deficiencies immidiately corrected or respectively repaired with in a short time limit.

- In plant 24, at the cutting room and the processing area sanitizers were not at 82°C temporarily. The local veterinary officer stopped the activities at the area and restarted after mechanical problem was fixed (the plant changed the broken pump).
In the same plant cross contamination was observed on finished carcasses during enter into blast freezer due to dirty plastic flaps touching each carcass. According to the size of carcasses a suitable size of opening was cut out from the plastic flaps. With this technical modification establishment found solution to prevent continuous cross contamination of carcasses.

- In plant 62 was condensation in carcass chiller under cooler, veterinary took correctiv action immidiately.
In the same plant in the cutting, deboning area the plastic containers collecting edible meat and bons were not identified. The plant management took appropriate action to mark the containers for edible and inedible products.

In connection with plant 7 I was just studiing U.S. final audit report to write our comments. when I received information from FSIS that, in salami procducts of veterinary control number 7 PICK Szeged Rt. Szalámigyár és Húsüzem were detected Listeria monocytogenes third time.

The Hungarian Veterinary Authority immidiatedly started to conduct investigation and stopped the export of the salami products to U.S. from plant 7.

At the same time instracted plant 7 to modify HACCP plan which would assure to find the cause of the Listeria monocytogenes contamination, control of the correctiv actions, containing specific measure to eradicate and prevent recurrence of contamination.

Also the effectivenes of SSOP program and procedures have to be controlled more stricky. At the time when those specific actions have been compleated, I will provide FSIS with a full riport containing corrective actions that the company has taken, to control Listeria monocytogenes contamination of salami product.

- For the competent official veterinary stations supervise U.S. certified plants I repeatedly forwarded 8-3-99 FSIS NOTICE giving instraction verifying the Listeria monocytogenes reassessment.

- In every U.S. certified plants the Listeria monocytogenes program implemented into HACCP plans.

- For determination of the Ca content of mechanical deboning meat a monitoring program was made and measures were taken for its documention.

Besides that, the smaller deficiencies – not written in the report – in all establishment had been corrected.

Thank you for your cooperation.

Sincerely

Dr. Antal Németh
Head of Department
Department of Veterinary and Food Hygiene

01 23

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	02-13-2002	05, Gyulai Huskombinat	Gyulai
			COUNTRY Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr.S.P.Singh	Dr.Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

M.05=No warm water supply in hand washing facilities in Locker-change rooms. Mechanical problem, immediately corrected.

Windows were not shut tight in locker rooms-potential for vermins and flies, immediately corrected.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
02-14-02	06, Papai Huskombinat	Papa
		COUNTRY: Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr.Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ 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

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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
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Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
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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	SSOP	A
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
02-25-2002	07, Pick Szeged	Szeged
		COUNTRY: Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr.S.P.Singh	Dr.Imre Ryda	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
02-18-2002	010, Ringa Huspari Rt	Kapuvar / Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S.P.Singh	Dr.Imre Ryda	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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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
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Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	COMMENTS MADE ON REVERSE	

FSIS FORM 9530-2 (12/93) REPLACES FSIS FORM 9530-2 (11/90) WHICH MAY BE USED UNTIL EXHAUSTED

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
02-19-2002	024, Falco Trade Rt.	Gyongyos
		COUNTRY: Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr. Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ 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

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Sanitizers	05 M	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
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Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
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Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	02-19-2002	024, Falco Trade Rt.	Gyongyos
			COUNTRY Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr. Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

M.05= Sanitizers were not at 82c in boning room in pork processing area. Government officials closed the area and restarted after mechanical problem was fixed.

M.28= Cross contamination was observed on finished carcasses ready to enter in blast freezer due to dirty plastic flaps touching each carcass.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
02-20-2002	062, Kometa 99 Kft	Kaposvar / Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr. Imre Ryda	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	02-20-2002	062, Kometa 99 Kft	Kaposvar
			COUNTRY Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr. Imre Ryda	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

17-M = Condensation in carcass cooler was dripping but on carcasses. Govt. of Hungary officials took correctivr action immedeately.

20-M = Plastic containers in boning and cutting rooms were not identified for edible and inedible products.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
02-21-2002	147, Pick Szeged Rt	Cegled
		COUNTRY: Hungary

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. S. P. Singh	Dr. Sandor Tili	☐ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable

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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		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	