



United States Department of Agriculture

MAY 6 2014

Food Safety and
Inspection Service

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Dr. Endre Kardevan
State Secretary
Ministry of Rural Development
Food Chain Control and Agricultural Administration
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H-1055 Budapest, Hungary

Dear Dr. Kardevan,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Hungary's Meat inspection system from April 9 through April 26, 2013. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Shaukat H. Syed".

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

HUNGARY
FINAL AUDIT REPORT

January 29, 2014

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an equivalence verification audit that included an on-site audit from April 8-25, 2013, by the Food Safety and Inspection Service (FSIS) to determine whether Hungary's food safety inspection system governing the production of meat remains equivalent to that of the United States, with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. The audit began with a thorough review of Self Reporting Tool (SRT) information provided by the Hungary National Food Chain Safety Office (NEBIH) as of 2013, Port-of Entry (POE) sampling results, and FSIS' 2008 audit report and Hungary's proposed corrective actions from 2008.

The audit was designed to determine the equivalence of Hungary's meat inspection system by examining not heat-treated (shelf stable) and fully cooked, heat-treated (non-shelf stable) product in two slaughter/processing establishments and one cutting establishment focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the April 2008 FSIS audit's observations were being implemented.

The on-site portion of the audit included two red meat slaughter/processing establishments producing ready-to-eat (RTE) meat products and one meat cutting establishment. Currently, Hungary has five certified establishments approved for U.S. export but only the three audited establishments export directly to the United States. These establishments export cured salami and ham. FSIS also audited six government offices, including the NEBIH headquarters, two county offices, and three in-establishment government offices. Two government laboratories conducting microbiological and chemical residue testing were also audited.

This audit found that Hungary's inspection system is performing "average" in maintaining its equivalence based on POE violations and audit observations. An examination of POE violations between January 1 and October 31, 2013, showed that 41 of the total 57 lots of meat products imported from two establishments were re-inspected. No food safety violations were found. This indicated that Hungary maintains good process control for product exported to the United States. Also, the CCA met the core criteria for all six equivalence components, though there was some need for improvement of oversight related to sanitation. At one audited slaughter/processing establishment, the FSIS auditor observed condensation problems that were caused by a malfunctioning cooling system. Corrective actions were taken immediately to correct sanitation issues. During the exit meeting, the CCA addressed the sanitation issues by ensuring that acceptable, immediate corrective actions were identified, and proposed follow-up long-term solutions were undertaken.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence verification audit of Hungary's meat inspection system that included an on-site visit from April 8 to 25, 2013. Hungary is eligible to export pork and pork products to the United States. Exported pork products include 03E Not Heat Treated/Shelf Stable RTE acidified/fermented product, 03F Heat Treated/Shelf Stable, and 03G RTE Fully cooked/Not Shelf Stable ham.

From January 1 to October 31, 2013, Hungary exported 424,478 pounds of pork products to the United States, of which 290,779 pounds were re-inspected. A total of 2,268 pounds were refused entry for "off condition" which is not a food safety concern. In 2012, the previous calendar year, Hungary presented 563,635 pounds of pork products of which 261,982 pounds were re-inspected with no refusals. During these periods, FSIS import inspectors re-inspected 41 of the total 57 lots of meat products imported from two establishments. The result was a single re-inspection type-of-inspection (TOI) failure (in May 2013) for product found to be off-condition, but there were no food safety failures. These observations indicate good process control.

The audit was conducted under the specific provisions of the 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.
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901 et seq.)

In addition, FSIS verified that Hungary was in compliance with implementation of the European Commission (EC) Regulations 852/2004; 853/2004; 854/2004; 882/2004; 2073/2004; 178; 20723; Council Directives 96-22 and 96-23.

The audit standards applied during the audit of Hungary's meat inspection system included all applicable legislation originally determined by FSIS to be equivalent as part of the initial equivalence evaluation process and subsequent equivalence determinations for the following:

- Testing for *Enterobacteriaceae* and total viable count in lieu of testing for generic *E. coli*, acceptable for all EU exporting countries.
- Testing for generic *E. coli*. Government laboratories analyze the samples.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Hungary's meat inspection system governing meat products continues to be equivalent to that of the United States (U.S.) with the ability to produce and export products that are safe, wholesome, unadulterated, and properly labeled. To achieve this goal, the audit focused on six equivalence components with the objective of determining if each area is and can maintain its equivalence: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS

verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the April 2008 FSIS audit's observations were being implemented.

III. AUDIT METHODOLOGY

For conducting this equivalence verification audit, FSIS utilized its established four-phase process: plan, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involved document and data review and analysis of previous audit observations and other available information. Therefore, prior to conducting the 2013 on-site audit, FSIS examined CCA's performance within six equivalence components largely from information obtained directly from the CCA through the Self Reporting Tool that addressed all components, including outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. In addition, the auditor examined data on exported product types and volumes, port-of-entry (POE) testing results, and other data collected by FSIS since the last FSIS audit in 2008. This comprehensive analysis served as the basis for planning the on-site audit itinerary.

The second phase is the on-site or execution phase. FSIS conducted this on-site audit to verify the CCA's activities as they relate to each equivalence component. The auditor gathered data on all six components through document reviews, interviews, and observations. The FSIS auditor was accompanied throughout the entire audit by representatives from the Central Competent Authority (CCA), the Ministry of Agriculture and Rural Development (MARD), including members from the state or establishment inspection offices.

Management, supervision and administrative functions were reviewed at the CCA headquarters, Baranya county (Pecs) government office directorate, Csongrad county (Szeged) government office directorate, and three establishments (two swine slaughter/processing and one swine cutting) to verify that the national system of inspection, verification, and enforcement was being implemented in an equivalent manner. There are five certified establishments approved for export of product to the United States—two slaughter/processing, one processing, one cutting, and one cold storage. Three of these five were selected for the audit based on the previous audit results, volume of the U.S. exports, POE results and the fact that only two establishments directly export product to the United States. During the establishment visits, particular attention was paid to the extent to which government verifies control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews of its inspection personnel.

The FSIS auditor assessed the CCA's oversight activities over approved chemical residue and microbiology laboratories during both the planning and the on-site audit phase. FSIS also reviewed laboratory-related data collected from the 2008 audit. In addition, FSIS conducted on-site interviews of inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters. An on-site visit to the laboratory associated with the chemical residue and microbiology testing programs was part of this year's itinerary.

The third phase was evaluation. FSIS conducted an evaluation of all data collected on-site to determine whether the CCA's performance design and execution was consistent with the information provided to FSIS via the SRT and other submitted documents. An extensive analysis of all data was used to determine the equivalence decision.

The final phase is a feedback phase, which begins with providing this draft audit report to the CCA to give them an opportunity for comment. After reviewing CCA's comments and responses to all observations, FSIS will prepare a final report. Then, an action plan will be developed to address any issues raised by the audit.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States. The evaluation of this component included an analysis of documentation previously submitted by the CCA as support for the responses and corrective actions provided in the SRT, on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments, as well as any follow-up documents.

After the general election in 2010, Ministry of Agriculture and Rural Development and Ministry of Environment and Water were merged into one ministry, the Ministry of Agriculture and Rural Development (MARD). Hungary's food safety organization is spearheaded by the MARD, which is led by the State Secretary for food chain control and agricultural administration and who also functions as a Chief Veterinary Officer (CVO). MARD is responsible for the general planning and supervision of food and veterinary controls at the Ministry level. The State Secretary and his Deputy are in charge of the following three departments: Department of Food Chain Control, Department of Food Processing, and Department of Forestry, Fishery and Game.

The Hungary National Food Chain Safety Office (NEBIH) operates under the auspices of MARD and its Minister. The NEBIH State Secretary for food chain control and agricultural administration and the CVO are responsible for directing food safety, plus animal health and welfare controls. The NEBIH at the HQ level has a President or Deputy CVO for Food Chain Control and Animal Health, as well as a Deputy President for Plant, Soil and Forest Protection. The Department of Food Chain Control that is directly under MARD supervision consists of the following four units: Animal Health and Coordination Unit, Food and Feed Safety Unit, Plant Protection and Soil Conservation Unit, and Legal Unit.

NEBIH at the county level consists of two directorates: Directorates for Food Chain Safety and Animal Health, and the Directorates for Plant Protection and Soil Conservation. At the county level, County Offices (CO) consists of units of the Directorates for Food Chain Safety and Animal Health. At the District level, District Offices (DO) consists of units of the Directorates for Food Chain Safety and Animal Health.

The NEBIH, a unit under the Ministry of Agriculture and Rural Development, is responsible for meat inspection of U.S. certified establishments. The NEBIH is managed by the Deputy President for Food Chain Control and Animal Health who is appointed by the Chief Veterinary Officer (CVO). The CVO is appointed by Minister of Agriculture and is the most senior level for veterinary and food inspection activities. The NEBIH HQ represents the first level of the inspection system and has a direct authority over the establishments that are certified for export to the United States. The county represents the second level of inspection. It has control over meat establishments within its jurisdiction and is headed

by the Director of the County Directorates for Food Chain Safety and Animal Health. The third level of inspection is sometimes handled by District offices and/or the in-plant inspection service.

Official verification and inspection activities are conducted at all certified establishments in accordance with uniform instructions disseminated from the CCA to the field via email, telephone, and hard copy. Updates and additional instructions to personnel concerning established regulations, programs, and manuals are published and disseminated as guidelines. These programs and manuals contain procedures to assist official personnel in uniformly assessing the adequacy of food safety measures implemented by establishments certified to export meat products from Hungary to the United States and enforce the regulations of the inspection system. The FSIS auditor performed on-site observations and reviewed records maintained by inspection personnel at headquarters, county offices, and in-establishment NEBIH inspection offices. Officials use the authority provided them by the laws of Hungary to enforce the rules of the meat inspection system, identify and document non-compliances, and verify the adequacy of corrective actions and preventive measures.

The enforcement strategies in place are based on EU regulation 882/2004. The CCA has controls in place to prevent fraud or misuse of export health certificates. The second level inspection offices—county offices—have control over meat slaughter and processing establishments in their jurisdiction.

The FSIS auditor verified that the CCA provides an ongoing training program to ensure that inspection officials are aware of specific inspection requirements that pertain to Hungary's meat exports to the United States. The FSIS auditor reviewed the inspection personnel's training records at the headquarters and local inspection offices. This review indicated that in-plant inspection personnel have completed classroom training similar to what FSIS inspectors receive.

The CCA is responsible for hiring and assigning qualified inspection personnel, based on *Statutes no. 38/EE/2006*, to perform inspection and enforcement activities at the certified establishments. The FSIS auditor reviewed documentation to ascertain that Veterinary Medical Doctors had the required veterinary degrees and that inspectors had the required pre-employment training program and education. This documentation was reviewed for a sampling of individuals including both veterinarians and inspectors at the headquarters and in-establishment levels. All training records reviewed showed that veterinary personnel had degrees in veterinary medicine and that inspectors had certificates attesting to their required pre-employment training programs. In Hungary, veterinarians take meat inspection courses in the curriculum of their formal education. After obtaining their degrees they attend post graduate courses for meat inspection, technology, and hygiene. Non-veterinary inspectors ("auxiliaries"), in accordance with EC regulation 854/2004, have inspection courses at the University or high school and on-job training.

The FSIS auditor verified that the CCA operations are funded by the government, in accordance with the EU Regulation 882/2004. The inspection personnel assigned at the establishments certified to export meat products to the United States are employees of the national government who are identified by identification (ID) cards. The auditor also confirmed compliance with the CCA's Act 199 of 2011 of Hungary, which provides the regulatory framework for payment for inspection activities. The auditor verified, through document review (i.e., pay stubs and ID cards) at the CCA, state office, and audited establishments, that inspection personnel assigned to certified establishments were employees of the government servicing agency, including national, state, and municipal governments.

FSIS' review of the inspection activities carried out at both levels of the inspection system indicated that the EC regulations are the primary overarching laws for regulating meat inspection, enforcing inspection laws, and ensuring that adulterated or misbranded products are not exported to the United States. In addition, Hungary has issued national legislation to address the implementation of inspection activities; the verification of the microbiological sampling; the performance of official inspection tasks; and the scope and method of carrying out the National Residue Control Plan in accordance with EC Directive 96/22 and 96/23. The CCA disseminates inspection information related to regulatory and administrative affairs electronically to establishments certified to export product to the United States.

According to the § 35 (3) b) of the following Hungarian national law: "Act 46 of 2008 on the food hygiene and its official control," the CCA has authority to certify and de-certify U.S. exporting establishments. Initial and annual ongoing certification of establishments for export to the United States is performed by the county officials of the CCA. The CCA has a written protocol that describes the procedures that establishment operators should follow to obtain approval from Ministry of Agriculture and Rural Development to become certified for export. The actions taken by government officials at each step of the approval process are clearly delineated. The CCA county officials conduct the initial export approval determinations through a comprehensive establishment audit which consists of review of the establishment's documentation including HACCP, sanitation, and sampling documents as well as one or more on-site visits to the establishment to verify that all regulatory requirements specific to an importing country have been met. If approved, county officials inform NEBIH that (noun missing here – who conducts?) conducts an additional audit and informs MARD to proceed with certification. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing U.S.-certified establishment to maintain its eligibility to export to the United States.

NEBIH may issue a verbal warning by the Veterinarian-In- Charge (VIC) of cancellation of approval of food premises to export the product to United States based on observations by inspection personnel of HACCP, SSOP, or other non-compliances and not meeting the time limits for corrections of non-compliances. If an establishment does not comply with a warning, then the establishment's export approval is removed.

The CCA demonstrated that it is capable of tracking export certificates issued for a specific country. This tracking system relies on the issuance of a unique identification number for each certificate and the maintenance of records that includes a signature card for each authorized veterinarian. In addition, export seals, stamps, and health certificates are secured at the official inspection office.

The laboratory system consists of eight government (NEBIH) laboratories that conduct analytical testing of product destined for the United States.

- Szekesfehervari Regional (County) Food Laboratory
- Miskolci Regional (County) Food Laboratory
- Debreceni Regional (County) Food Laboratory
- Kecskemeti Regional (County) Food Laboratory
- Szekszardi Regional (County) Food Laboratory
- Kaposvari Regional (County) Food Laboratory
- Veszpremi Regional (County) Food and Microbiology Laboratory

- Szombathelyi Food Radioanalytical Laboratory

The Chemistry and Toxicology Laboratory, a government (County) laboratory, is responsible for conducting national residue analyses and conducting microbiological testing for exporting establishments. The FSIS auditor visited the Chemistry and Toxicology Laboratory in Budapest, which has been identified as the National Reference Laboratory for all commodities and all substance groups listed in Annex 1 of Council Directive 96/23/EC. This laboratory is accredited according to ISO 17025 and is reviewed by Hungarian National Accreditation Board (NAT). The CCA, as part of its oversight responsibilities, conducts annual reviews and audits of the laboratories which are responsible for testing of product destined for export to the United States. The CCA annual audit report includes administrative and technical aspects of the analytical methodology, laboratory personnel qualifications and training, and maintenance of the laboratory equipment. The FSIS auditor reviewed the CCA audit reports and its related follow-up reviews. No concerns arose as the result of these reviews. NEHIB funds the laboratory analysis, while the county funds the inspection personnel salaries.

The CCA has authority for official control over establishment construction, facilities, and equipment according to the Act, paragraph 35 (3) c) of the following national law: “Act 46 of 2008 on the food hygiene and its official control.” This part of the Act states that the food-chain authority controls the food-producing and distributing establishment suitability to export to third countries, according to the international requirements.

The CCA’s authority to enforce inspection laws is specified in Hungary’s Act 48 of 2008 and Government Decree 328/2010 of December 27. In addition, the CCA has the legal authority and the responsibility to write, implement, and enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. To achieve these objectives, the CCA issues, distributes, and enforces a number of official circulars that offer inspection-related guidelines and instruction to its inspection personnel.

The FSIS auditor reviewed non-compliance reports (NRs) that were generated by in-plant inspection personnel at all three audited establishments. FSIS noted that the inspection personnel had identified and documented deficiencies in NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment’s corrective actions and preventive measures. The auditor verified that the inspection personnel have adequately described non-compliances and verified the effectiveness of the establishment’s corrective actions. The FSIS auditor also reviewed the last six months of written periodic supervisory reviews to assess the enforcement capability of the inspection personnel and the adequacy of the establishment’s corrective actions. The conditions in the audited establishments matched the supervisory reviews, and no non-compliance trends related to SSOP, HACCP, SPS, or slaughter activities were observed.

FSIS requires that documented periodic supervisory reviews be performed in all establishments eligible for export to the United States according to the 9 CFR 327.2 (iv)(A). The auditor verified implementation of these reviews at the CCA headquarters, the county office, and all audited establishments. In the two swine slaughter/processing and one cutting establishment audited, periodic supervisory reviews were conducted quarterly by the county veterinary supervisors employed by NEBIH. An action plan was written to address needed corrective actions after the quarterly review. The

VIC who verifies the corrective action follows up within one month after negative observations. HQ performs supervisory reviews every six months.

In all locations, the supervisory reviews were conducted using a standard form that consists of a checklist. This form was used for evaluating the adequacy of the establishment's food safety system, including items related to inspection verification of SPS elements, SSOP, HACCP, and microbiological control (i.e., *E. coli*, *Salmonella*, and *E. coli/Enterobacteriaceae*). Additionally, the form consists of questions for evaluating the knowledge, skills, and abilities of inspection personnel to conduct assigned responsibilities at U.S.-eligible establishments. The periodic supervisory review reports are distributed to the audited establishment's management and the related county office. The Veterinarian-In-Charge (VIC) is responsible for verification of corrective actions resulting from the review. The county office is responsible for analyzing the results of the review.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The CCA has adopted requirements that are the same as FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416 and are directly implemented by the Hungarian inspection system. The in-plant inspection personnel at all audited establishments verified sanitary conditions that included the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review and hands-on verification inspection of both pre-operational and operational procedures. Instructions are provided by the CCA to the official inspection personnel to conduct a continuous and systematic assessment of inspection activities during routine verifications of sanitation issues, including: maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits and workers' health; and operational sanitary procedures.

Therefore, after a thorough review of all documents, on-site observations and interviews, the auditor concluded that Hungary's government has in place an "average" equivalent organizational structure for performing oversight.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to U.S.-eligible establishments. The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. The FSIS auditor verified that official inspection and verification activities were in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA as outlined in official legislation, circulars, and other instructions issued in accordance with

NEBIH inspection law. The auditor confirmed that the CCA provided the county's and county establishment inspection offices with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to U.S.-eligible establishments.

During the on-site audit of two swine slaughter/processing establishments, the FSIS auditor accompanied and observed the in-plant inspection verification activities for operational sanitation procedures, HACCP verification activities including the zero tolerance CCP verification, as well as ante-mortem/humane handling and slaughter, post-mortem examination, *Salmonella* spp. and generic *E. coli/Enterobacteriaceae* sample collection. In addition, during the on-site audit of one swine cutting establishment, the FSIS auditor reviewed and observed the in-plant inspection verification activities for RTE sampling and testing.

The FSIS auditor verified that in-plant VIC conducted ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents, including animal identification documents. In accordance with procedures and requirements, the VICs observed all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter. Each establishment had a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals had access to water in all holding pens (including that used for suspect animals); if animals were held overnight, feed and water were provided. The implementation of the ante-mortem inspection complied with Hungary's (EU) Regulation No. 853/2004 and 854/2004 -Ante-mortem Inspection that has been determined equivalent and is directly applicable by the inspection system of the country. The FSIS auditor further verified through on-site record review, interviews, and observations that the CCA's requirements concerning ante-mortem and humane handling/slaughter of livestock were met in the two audited slaughter/processing establishments.

FSIS assessed post-mortem inspection examinations through on-site record review, interviews, and observations of inspection activities in the two audited slaughter/processing establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. Both in-plant veterinary and non-veterinary inspectors were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes were made. These actions were in accordance with Hungary's adoption of (EU) "Regulation No. 853/2004 of the European Parliament and of the Council laying down specific rules for food of animal origin" and "Regulation 854/2004 of the European Parliament and of the Council issuing specific rules for the organization of official controls on products of animal origin intended for human consumption"- post-mortem inspection, which have been determined equivalent. The design of the post-mortem inspection stations including proper lighting and the number of on-line inspectors was in accordance with inspection requirements. The FSIS auditor also observed the functions of the off-line veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities in these two audited establishments. These daily verification activities included direct observation, measurement, and review of establishments' records, including

HACCP, sanitation SOP and SPS, and *E. coli/Enterobacteriaceae* and *Salmonella* carcass sampling records.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The in-plant inspection personnel at three audited establishments verified sanitary conditions in accordance with methodology described in the CCA's Article 4.2. Of the EU Regulation No 854/2004 EC/as well as in paragraph 35 (3) c) of the following national law: "Act 46 of 2008 on the food hygiene and its official control" on monitoring and implementation of sanitation procedures, record review and hands-on verification inspection of both pre-operational and operational procedures. This Regulation and Law provided instructions to the official inspection personnel to conduct a continuous and systematic assessment of inspection activities during routine verifications of sanitation issues, including: maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits and workers' health; and operational sanitary procedures.

FSIS also assessed the adequacy of HACCP program verification activities conducted by inspection officials and establishment personnel at the establishment level, by observing verification activities and reviewing monitoring and verification records generated by establishment and in-plant inspection personnel at all audited establishments. Hungary's meat inspection system has legal authority and a "well" documented regulatory framework to implement requirements equivalent to those governing the U.S. system of meat inspection. The analysis and audit verification activities indicated that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component and operates at an "average" level of performance.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was sanitation. The inspection system must provide requirements for all areas of sanitation, sanitary handling of products and Sanitation Standard Operating Procedures (SSOPs). Prior to the on-site visit, the auditor reviewed Article 4.2. of the Regulation No. 854/2004/EC/ submitted by the CCA in the SRT. Once on-site, the auditor gathered additional information at the government offices and the three audited establishments.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the three audited establishments. In one of the slaughter/processing establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of cutting establishment areas. The in-plant hands-on verification procedures started after the establishment personnel conducted its pre-operational sanitation and determined the facility was ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection person conducted this activity in accordance with the established procedures which FSIS has determined to be equivalent to those of the United States (9 CFR 416.13 (a) "Implementation of SOPs").

In addition, the FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at all three audited establishments. These verification activities included direct observation of operations and review of establishment records. The FSIS auditor also reviewed the establishment's sanitation monitoring and the corresponding verification records for approximately three months that are maintained by the inspector. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees specified as being responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. The following sanitation non-compliances were observed by the FSIS auditor and corrected by the inspection service:

- In one slaughter/processing establishment, the FSIS auditor observed dripping condensation over the exposed carcasses at the "blast freezer." The CCA tagged the blast freezer. The establishment took corrective action by removing and trimming affected carcasses and moving them to different freezer. Additionally, the establishment replaced the malfunctioning cooling system unit.
- In the cutting establishment, the FSIS auditor observed a space under the hallway door leading to the outside premises that created a potential entrance for insect or rodents. No evidence of rodent droppings was observed.

The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOPs by adopting 9 CFR 416. This document, adapting SSOP, was published in "Horizontal Guide for checking specific export requirements" issued in June 2008 by CCA. Local and county officials can find this guide through the intranet system of CCA.

In-plant veterinary officials and state supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions with the noted exceptions above. Non-compliances that required immediate corrective action were corrected immediately and non-compliances requiring long term corrective action (malfunctioning cooling system) were scheduled for follow-up oversight. The audit observations support that the CCA operates at an "adequate" level of performance in meetings its equivalence determination.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. To maintain equivalence, the meat inspection system must require that each official establishment develop, implement, and maintain a HACCP system or equivalent preventative program for each operation.

The CCA's headquarters, two NEBIH county offices, and three establishments were visited to determine whether the NEBIH inspection offices maintained effective government oversight for the implementation of the CCA's meat inspection system and, in particular, HACCP requirements. Hungary's meat inspection system has adopted the following EU regulation for U.S.-eligible

establishments: FSIS has determined that Regulation 854/2004/EC as well as 852/2004/EC, in which HACCP regulatory requirements are prescribed, are equivalent to 9 CFR Part 417. The differences in the HACCP observations were mainly related to the prerequisite programs, the way they are documented and verified, and the scope and content of the identification of a hazard, but the exporting establishments use the U.S. model of HACCP.

The FSIS auditor verified through record review and observation that the in-plant inspection personnel at the certified establishments conducted daily verification of HACCP plans in accordance with methodology described in the CCA's Official Guide, currently the 5th edition by the NFCSO, which included the evaluation of written HACCP programs, monitoring, verification, corrective actions, record keeping, and hands-on verification inspection.

At the two slaughter/processing establishments; the FSIS auditor conducted a review of the zero tolerance for feces, ingesta, and milk by reviewing CCP records generated over the past six months. At both establishments, inspection monitoring and verification records documented some deviations from the critical limits of some CCPs. All parts of the corrective actions were implemented in accordance with Regulation 854/2004/EC as well as 852/2004/EC in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417. These were published in a document called "Horizontal Guide for checking specific export requirements" issued in June 2008 by CCA. Local and county officials can find this guide through the intranet system of CCA.

The U.S. HACCP requirement requesting the U.S.-eligible establishments to implement preventive measures to deviation were addressed by slaughter/processing establishment employees and verified by the inspection personnel. No non-compliance trends were detected. The FSIS auditor verified the physical CCP location by observing inspection personnel conducting HACCP hands-on verification activities, as well as performing an independent direct monitoring examination of pork carcasses at the establishment. No deviations from the critical limits were observed by the FSIS auditor. The FSIS auditor also verified that the zero tolerance CCP location met the CCA's requirement for proper examination. Based on review of documents at the government offices and establishments, as well as interviews with official personnel, the FSIS auditor did not identify any concerns.

In conclusion, the assessment of the HACCP programs demonstrated that the CCA's inspection system provides requirements equivalent to those of FSIS' HACCP regulatory requirements and adheres to the requirements during implementation. The auditor determined that HACCP export requirements were met in all establishments audited and during other data reviews, therefore the HACCP component is determined to be performing at an "average" level.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth equivalence component. To be equivalent, the program must include the following components: random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the process used to design the plan. The CCA must provide a description of the actions taken to address unsafe residues as they occur. The CCA must

provide oversight of laboratory capabilities and analytical methodologies to assure the validity and reliability of test data.

FSIS' residue experts thoroughly reviewed documentation pertaining to the design and implementation of CCA's National Residue Program (NRP). The in-depth review included an analysis of the 2012 and 2013 residue monitoring plan as well as additional responses outlining the structure of Hungary's chemical testing program provided in the SRT. The auditor also conducted an on-site audit of one residue laboratory that performs residue analysis according to the Hungarian requirements deemed to be equivalent to the U.S. requirements.

The auditor reviewed the information in the SRT and verified that the inspection system has an organized governmental program established to carry out effective regulatory activities to prevent contamination of meat products with chemical residues. The various elements of the program are conducted by the CCA in conjunction with the government laboratories located in Budapest. The auditor also verified the previously submitted laws, regulations, and implementation documents defining the legal authority of the CCA to organize and implement a residue control program. This legal authority prescribes the conditions for the use of chemicals in the production of meat products, prohibits the use of compounds that may present unacceptable public health risks, and provides the ability to control and monitor industrial and environmental chemicals that may lead to contamination and provides the ability to enforce these laws and regulations.

The FSIS auditor verified that CCA conducts annual audits of their residue laboratories that perform analysis of products that are destined for export to the United States. During the CCA's headquarters audit, the FSIS auditor interviewed NEBIH officials and reviewed the following 2013 laboratory audit reports: Annual Monitoring Audit of Central Residue/Toxicology Laboratory in Budapest and other county laboratories (Veszprem and Kecskemet County Complex laboratories). These are government residue laboratories that conduct chlorinated hydrocarbons (CHC), polychlorinated biphenyl (PCB), organophosphates (OP), Di-Ethyl-Stilbene (DES), Antibiotics (AB) and Sulfonamides (S) testing. The FSIS auditor found appropriate responses and no concerns with the CCA's chemical residue program.

Additionally, the FSIS auditor verified that CCA also conducts random sampling and testing of internal organs, muscle, and fat for targeted residues. The auditor verified that the implementation of the current year's sampling plan was implemented as outlined in the National Residue Plan.

The FSIS auditor also conducted follow up verification of the corrective actions taken by the CCA in response to the FSIS 2008 audit observations (i.e., temperatures of incoming meat samples were not measured or documented as required, and the official standards book for preparation of stock solution was missing verification data).

FSIS auditor verified that government sampling is performed by the official veterinarian who packs all tissues separately and sends them to the central or county laboratory in a refrigerated vehicle. If the sample is refused by the laboratory, a new sample is collected. The central laboratory in Budapest oversees the county and private laboratories. Government laboratories in Hungary perform both intra- and inter-laboratory testing. International testing is performed by EU reference laboratory. The withdrawal period is based on the specific requirement for the particular compound. Accreditation by "Nemzeti Akkreditáló Testület" (NAT) is performed every fourth year.

The CCA's meat inspection system has regulatory requirements for a chemical residue control program that continue to demonstrate the ability to meet the core equivalence requirements for this component. Both the document analysis of the National Residue Control Program and on-site audit verification activities indicate that Hungary's meat inspection system has regulatory requirements designed and administered in accordance with requirements and standards determined to be equivalent by FSIS. The CCA operates at an "average" level of performance and no residue POE violations were observed for a period of 3 years.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome and meet all equivalence criteria.

The evaluation of this component included a review and analysis of the CCA's Ministerial Circular No 21.602/1/1997 "*Sampling of carcasses for testing for generic E. coli*" previously submitted by the CCA as support for the responses provided in the SRT. This circular describes the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological tests. There are two circulars published for *Salmonella* spp. Analysis "*51.001/99 National Food Inspection Institute (OEVI) circular*"-Rules for carcass sampling for the testing of *Salmonella* spp," and 51.325/1999 OEVI circular- "*Salmonella* spp. in the HACCP system." Additionally, the following circulars are issued on the *Lm*: "995/000/OEVI/2003, OEVI Circular- *Listeria monocytogenes* guidelines of the FSIS"; "1082/OEVI/2003-Circular-Special rules concerning *Listeria monocytogenes*" and "Testing Programs for RTE products (*Lm*, *Salmonella* spp., *E. coli*).

The FSIS auditor accompanied and observed the in-plant inspection verification activities for *Salmonella*, *Enterobacteriaceae* and generic *E. coli* sample collection in two slaughter/processing establishments. In addition, the auditor observed and verified the implementation of *Lm* sampling program in one of these two establishments. The auditor visited one microbiological laboratory in Budapest.

The CCA has a *Salmonella* testing program for carcass sampling that meets FSIS *Salmonella* Performance Standards requirements cited in 9 CFR 310.25(b). The CCA requires that one *Salmonella* set be scheduled by daily collection of one sample up to 50 and then by weekly collection, which consists of 55 samples from swine carcasses with up to six positive samples being acceptable in swine. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States. The suspension remains in effect until the establishment identifies the cause, takes proper corrective actions and preventive measures, and achieves the performance standard set based on the number of samples tested (n) and the maximum number of positives to achieve standard (c). The CCA's *Salmonella* performance standard for swine (n = 55, c ≤ 6) is the same as FSIS' standards.

The CCA conducts verification activities that monitor an establishment's generic *E. coli* testing program in chilled swine carcasses. The testing program complies with FSIS equivalence criteria. While on-site

at two establishments, the FSIS auditor observed sampling and verified that the responsible individuals had the knowledge and skills to implement this type of testing on an ongoing basis. Similarly, both establishments and inspection personnel were familiar with the upper and lower control limits, as well as the corrective actions when the upper limits were exceeded. No loss of process control was identified during the on-site audits or noted in the past six months of documents reviewed.

The FSIS auditor verified that the CCA requires that establishments exporting RTE products to the United States have a program in place to meet FSIS equivalence criteria for control of *Lm*. The two processing establishments audited utilized the FSIS *Listeria* Compliance Guideline to formulate their *Listeria* programs. In addition, the CCA had a verification-testing program in place to test for *Lm* and *Salmonella* species in products that are eligible for export to the United States. Both were deemed equivalent.

FSIS confirmed that FSIS' equivalence criteria for RTE *Lm* control programs require the CCA verify implementation and effectiveness of control measures in each establishment certified for export to the United States, as stated in "Notification of Changes to the FSIS' Equivalence Criteria - Control Program for *Listeria monocytogenes (Lm)* in Ready-to-Eat (RTE) Products" dated July 13, 2011. This document stipulates verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment for *Lm* at a frequency that ensures that the establishments' control measures are effective. Based on the FSIS auditor's interviews and review of inspection documents at the CCA headquarters in Budapest, Szeged County Office, two RTE establishments, and Central Laboratory in Budapest, the FSIS auditor concluded:

- The RTE product testing is performed by the government for *Lm* and *Salmonella* three times a year according to the equivalent plan.
- The methods utilized by the CCA to confirm the presence of *Lm* in RTE product is in accordance with "FSIS Method MLG 8.07" and *Salmonella* detection utilizes the equivalent method MSZEN ISO 6579:2006.
- The CCA lab personnel collect a 325 gram sample for *Salmonella* and a 25 gram sample for *Lm* – an equivalent procedure.
- Establishments inform VIC if any positives result from testing product for *Lm* and *Salmonella*, as prescribed for equivalence.
- If the product is testing positive for *Lm*, the entire production lot is excluded from the export to the United States, as required under equivalence. Additionally, when product is prepared for U.S. export, domestic product is produced under time and space separation.
- The CCA maintains a regulatory definition for achieving lethality in RTE products by smoking and curing non-heat treated salami and by cooking of the ham according to 9 CFR 318. The CCA considers RTE products that test positive for *Lm* and RTE products that come into contact with food contact surfaces that have tested positive for *Lm* to be adulterated from either an establishment test or a government test. Establishments have to report all positive *Lm* and *Salmonella* results to the government inspector.

The audit focused on application of the approved FSIS Microbiology Laboratory Guidebook (MLG) methods: calibration of equipment, internal audits, traceability of samples and sample analysis, ISO 17025 requirements, and verification of corrective actions for non-compliances. The FSIS auditor found no concerns after reviewing the two most recent annual laboratory audit reports. Hungary's meat

inspection system has regulatory requirements for a microbiological testing program that are designed and administered in accordance with requirements and standards determined to be equivalent by FSIS. At this time, the CCA's microbiology testing program operates at an "average" level of performance.

X. CONCLUSIONS AND NEXT STEPS

This audit found that Hungary's inspection system is performing "average" in maintaining its equivalence based on POE and audit observations. An examination of POE violations between January 1 and October 31, 2013, showed that 41 of the total 57 lots of meat products imported from two establishments were re-inspected; no food safety violations were found.

Hungary is showing good process control for product exported to the United States. Also, the CCA met the core criteria for all six equivalence components. At one audited slaughter/processing establishment, the FSIS auditor observed condensation problems that were caused by a malfunctioning cooling system. Corrective actions were taken immediately by the establishment. During the exit meeting, the CCA presented regulatory action taken and provided evidence of the replacement of the cooling system pump. That corrective action was completed and the CCA discussed proposed follow-up actions. Consequently, FSIS requests that the CCA verify the adequacy of implementation of these above-noted corrective actions and include the documentation in response to this report.

APPENDIX A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PICK SZEGED Szalamagyar es Husuzem Zrt. 204 Siklosi ut 3 PECS - 7622 Hungary	2. AUDIT DATE April 11, 2013	3. ESTABLISHMENT NO. H-22	4. NAME OF COUNTRY Hungary
	5. NAME OF AUDITOR(S) Oto Urban, 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	X
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	X
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	0	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Date: April 11, 2013 Est #: H-22 (Pick. [P]) (Pecs, Hungary)

38/51 During the on-site inspection, the FSIS auditor observed a hole under the door at the hallway communicating with the outside premises, which was a potential entrance for insect or rodents. This was scheduled for immediate corrective action by the establishment management EU Reg. 854/2004, Annex I, Part B, Chapter I, 2 (c).

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

by *[Signature]* 04/11/2013

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PAPAI HUS 1913 Elemiszertipari Feldolgozo PAPA HU-6 Hungary	2. AUDIT DATE April 15, 2013	3. ESTABLISHMENT NO. HU-6	4. NAME OF COUNTRY Hungary
	5. NAME OF AUDITOR(S) Oto Urban, 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.	X	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	X
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	X
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	
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

Date: April 15, 2013 Est #: H-6 (Papa, [S/P]) (Papa, Hungary)

10/51 During the on-site tour, the FSIS auditor observed dripping condensation over the exposed carcasses at the "blast freezer", which brings temperature sharply down. The CCA representatives took immediate corrective action and establishment management implemented the inspection service instruction by removing all carcasses to the different room and by trimming affected carcasses in the different room. On April 16th, the deficiency was determined as failure of the malfunctioning cooling unit which was replaced by the establishment EU Reg. 853/2004, Annex III, 1(a).

46/51 The FSIS auditor observed heavy beaded condensation over the door entering to the suspect carcass cooler. This deficiency was corrected immediately by removing the overhead condensation by the establishment management EU Reg. 853/2004, Annex III, 1(a).

46 During the on-site inspection, the FSIS auditor observed that water in the sterilizer was bellow 82C. This non-compliance was requested to be corrected and it was immediately corrected by the establishment operator EU Reg. 853/2004, Chapter III, 5.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

by  DVM 04/15/2013

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PICK SZEGED ZrT. H-6725 Szeged, Szabadkai ut 18. Szeged, Hungary	2. AUDIT DATE April 18,	3. ESTABLISHMENT NO. HU-7	4. NAME OF COUNTRY Hungary
	5. NAME OF AUDITOR(S) Oto Urban, 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 SSOPs 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	X
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	X
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	
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

Date: April 18, 2013 Est #: HU-7 (Pick. [S/P]) (Szeged, Hungary)

45/51 During the pre-operational, on-site audit, the FSIS auditor observed pieces of meat and fat on the Christmas tree hangers at the processing room. This non-compliance was corrected immediately by the establishment management EU Reg. 853/2004, Chapter V, 2.

61. NAME OF AUDITOR

for Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

by *[Signature]*, DVM 04/18/2013

APPENDIX B: Foreign Country Response to Draft Final Audit Report



VIDÉKFEJLESZTÉSI
MINISZTERIUM

DR. KARDEVÁN ENDRE
államtitkár, országos főállatorvos

Iktatószám: ÉlfF/ 220 - 5 /2014.

Ügyintéző: Racskó Tamás
Telefonszám: 061-795-38-59
E-mail: tamas.racsko@vm.gov.hu
Hivatkozási szám:

Dr. Shaukat H. Syed
Igazgató úr részére
International Audit Staff
Office of Investigation, Enforcement and Audit

Food Safety Inspection Services
USDA-FSIS

Washington, D.C.
1400 Independence Avenue, S.W.
20250

Tárgy: Végleges jelentéstervezet véleményezése – kérés FSIS-től

Kedves Dr. Shaukat H. Syed,

Az Élelmiszerlánc-felügyeletért és Agrárigazgatásért felelős Államtitkarság tiszteletteljes üdvözlését küldi tisztelt Szolgálatára és személyesen az Ön részére.

Tájékoztatom, hogy megérkezett Szolgálatunkhoz a 2013. áprilisában lefolytatott magyarországi helyszíni ellenőrzésről készült végleges jelentés tervezete. Ezzel kapcsolatban jelzem, hogy hatóságunk áttekintette a dokumentumokat és nem tesz észrevételt az FSIS dokumentációjához. Annak érdekében, hogy folytassuk a megkezdett munkát, tisztelettel kérem, hogy legyen szíves a jelentés végleges változatát elküldeni hatóságunk részére.

Ezúton is köszönöm szíves visszajelzését, és bízom benne, hogy lehetőségünk lesz együttműködésünk bővítésére.

Kérem, fogadja őszinte nagyrabecsülésem.

Tisztelettel,



Dr. Kardeván Endre

Courtesy translation

*For Mr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit*

3rd April 2014

*Food Safety Inspection Services
USDA-FSIS*

Washington, D.C.

1400 Independence Avenue, S.W.
20250

Subject: Draft final audit report – request from Hungary

Dear Mr. Syed,

The State Secretariat for Food Chain Control and Agricultural Administration of the Hungarian Ministry of Rural Development presents its compliment to your respected Services and to you personally.

We have received the draft final audit report about the local audit carried out in Hungary in April 2013. I hereby would like to inform you that the Hungarian Services investigated the documents and do not have any comments on the findings of FSIS. In order to proceed with our work I hereby would like to ask your kind cooperation in sending us the final audit report.

I would like to thank you for your kind reply in advance and I hope that we will broaden our fruitful cooperation in the future.

Please accept the assurance of my highest consideration.

Yours sincerely,

Endre Kardeván DVM