



United States Department of Agriculture

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Food Safety and  
Inspection Service

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Dr. Lajos Bogнар  
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Ministry of Agriculture  
Food Chain Control and Agricultural Administration  
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Dear Dr. Bogнар,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Hungary's meat inspection system from June 15 through July 3, 2015. No comments were received from the Government of Hungary within 60 days. Enclosed is a copy of the final audit report.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

If you have any other questions, please feel free to contact me directly.

Sincerely,

  
for Jane H. Doherty  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
HUNGARY

JUNE 15 TO JULY 3, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
MEAT PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

February 1, 2016  
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 June 15 to July 3, 2015, by the Food Safety and Inspection Service (FSIS). The audit was 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 review of the Self Reporting Tool (SRT) information provided by the Hungary National Food Chain Safety Office (NEBIH) as of July 2015, Point-of Entry (POE) sampling results, and FSIS' audit report and Hungary's proposed corrective actions from 2013.

The audit was designed to determine the equivalence of Hungary's meat inspection system by examining not heat-treated (shelf stable) smoked; fully cooked-not shelf stable; and heat-treated, not fully cooked (non-shelf stable) products in two slaughter/processing establishments, one processing establishment, and one cold storage establishment. The audit focused on verification of six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the April 2013 FSIS audit 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, one meat processing establishment producing RTE product, and one cold storage establishment. Currently, Hungary has five certified establishments approved for United States export, but only three establishments export directly to the United States. These establishments export cured meat products including smoked salami, bacon, and ham.

FSIS also audited six government offices, including the NEBIH headquarters, one county office, and four in-establishment government offices. Two government laboratories conducting microbiological and chemical residue testing were also audited. An examination of POE data between April 1, 2014, and March 31, 2015, showed a total of 1,176,873 pounds of meat products were shipped to the United States with no food safety violations found.

- Several SPS non-compliances were identified and reported as corrected by the CCA to the auditor.

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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 June 15 to July 3, 2015. Hungary is eligible to export pork and pork products to the United States. Exported pork products include Not Heat Treated/Shelf Stable Ready-To-Eat (RTE) salami products; Heat Treated/not fully cooked, not shelf stable, bacon; Shelf Stable and RTE Fully cooked/not Shelf Stable, ham and shoulder.

An examination of Point-Of-Entry (POE) data between April 1, 2014, and March 31, 2015, showed that 95 % of the total of meat products imported into the United States was produced from two establishments that were re-inspected. A total of 1,176,873 pounds of meat products were shipped to the United States with no food safety violations found.

## **II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

This was an on-going equivalence verification audit. The audit objective was to ensure that the food safety system governing pork products maintains equivalence to that of the United States' food safety system, with the ability to export products that is safe, wholesome, unadulterated, and correctly labeled and packaged. Because of the APHIS restriction, beef product has not been exported to the United States. There are no establishments producing beef products for export to the United States at this time. Consequently, this audit did not include a visit to any bovine facilities.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, previous audit reports, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through a self-reporting process.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA or representatives from the County Government Directorate (Hungarian name: Veszprem County Government Office Directorate), and staff from inspection offices located within the audited establishments. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

The auditor reviewed the administrative functions at the CCA headquarters in Budapest, one county office, and local inspection offices at four establishments. During the review, the FSIS auditor evaluated implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement are being implemented as intended. The auditor conducted reviews of the administrative functions of local inspection

offices as part of the establishment review. The FSIS auditor assessed the administrative functions of sampling and testing through a review of records at the CCA’s headquarter office, county, and local offices. The auditor further assessed sampling and testing methodology through document review and observations at the central laboratory and three inspection offices. The fourth inspection office is at a cold storage facility that did not conduct microbiological testing.

A sample of the four establishments was selected from five establishments certified to export to the United States. During the establishment visits, the auditor paid particular attention to the extent of interaction between industry and government related to control hazards and prevention of non-compliances that could threaten food safety. The audit emphasized the Government Veszprem Inspectorate (GVI)’s ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2. The Hungarian National Reference Laboratory (HNRL) also known as Chemistry and Toxicology Laboratory in Budapest was audited to verify its ability to provide adequate technical support to the inspection system.

#### Audit Scope Summary

Competent Authority Visits		#	Locations
Competent Authority	Central	1	NEBIH/Budapest
	County Offices	1	County Government Office Directorate in <ul style="list-style-type: none"> <li>• Veszprem</li> </ul>
	District Offices	0	District Veterinary Inspectorate offices
	Local Offices	4	local inspection offices in: Papa, Szeged, Alsomocsolad, Dunakeszi
Government Laboratories <i>(microbiological and residue testing)</i>		2	The food Chemistry and Microbiology laboratory (OEVI) in Budapest
<b>Establishments</b>			
Pork slaughter/processing		2	<ul style="list-style-type: none"> <li>• Est. 6, Papa</li> <li>• Est. 7, Szeged</li> </ul>
Pork processing		1	<ul style="list-style-type: none"> <li>• Est. 86, Alsomocsolad</li> </ul>
Cold storage		1	<ul style="list-style-type: none"> <li>• Est. 55, Dunakesz</li> </ul>

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, and
- 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.

### **III. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)**

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.

In 2010, the Ministry of Agriculture and Rural Development and Ministry of Environment and Water were merged into one ministry, which was re-named the Ministry of Agriculture (MA) in 2014. Hungary's food safety organization is spearheaded by the MA, which is led by the State Secretary for food chain control and agricultural administration, and functions as a Chief Veterinary Officer (CVO). MA is responsible for the general planning and supervision of food and veterinary controls at the Ministry level. The State Secretary and Deputy Secretary 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 MA 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 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. County Offices (CO) and District Offices (DO) are composed of units of the Directorates for Food Chain Safety and Animal Health. The NEBIH is responsible for meat inspection at United States certified establishments. The Deputy President manages the NEBIH for Food Chain Control and Animal Health who is appointed by the Chief Veterinary Officer (CVO). The CVO is appointed by the 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 to export to the United States. The county represents the second level of inspection. The county controls meat establishments within its jurisdiction and is headed by the Director of the County Directorates for Food Chain Safety and Animal Health. District offices and the in-plant inspection system are the third level of inspection and are used when a county's territory is large.

The NEBIH provides training to County Offices on the subject of third countries' (including United States) requirements for Sanitation Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP), generic *E. coli*, and *Salmonella*. The CO supervisory reviews of establishments certified to export to the United States are conducted quarterly. In case of non-compliance, an Action Plan is requested, and the in-plant veterinarian verifies corrective action.

Official verification and inspection activities are conducted at all certified establishments in accordance with instructions disseminated from the CCA NEBIH 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 in enforcing the regulations of the inspection system.

The FSIS auditor performed on-site observations and reviewed records maintained by inspection personnel at headquarters, county/district 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 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 headquarters, county, and local inspection offices. This review indicated that in-plant inspection personnel have completed classroom training similar to what FSIS inspectors receive on the subject of animal and public health diseases. In addition, the CCA documents training on public health and animal health topics. This information is disseminated to the in-plant inspection personnel.

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 postgraduate 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 level as well as on-the-job training.

The FSIS auditor verified that the government, in accordance with the EU Regulation 882/2004, funds CCA operations. The inspection personnel assigned to the establishments certified to export meat products to the United States are employees of the national government and carry identification (ID) cards. The auditor also re-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 at the CCA, Veszprem county office, and audited establishments, that inspection personnel assigned to certified establishments were employees of the government-servicing agency. The government Certifying Organization provides payment of salaries to inspection personnel including overtime.

FSIS’ review of Hungary’s inspection activities carried out at both levels of the inspection system (HQ and CO) 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. Additionally, 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 instruction 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 Hungarian national law: “Act 46 of 2008 on the food hygiene and its official control,” the CCA has the authority to certify and de-certify United States exporting establishments. The county officials of the CCA perform initial and annual ongoing certification of establishments exporting to the United States. The CCA has a written protocol that describes the procedures that establishment operators should follow to obtain approval from the Ministry of Agriculture to become certified to export to the United States.

The actions taken by government officials at each step of the approval process are clearly described. The CCA county officials conduct the initial export approval determinations through a comprehensive establishment audit, which consists of a review of the establishment’s documentation including HACCP, sanitation, and sampling documents as well as 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. After conducting one or several on-site audits for United States approval, NEBIH informs MA to proceed or deny the certification. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing United States certified establishment to maintain its eligibility to export to the United States.

NEBIH may issue a verbal warning through the Veterinarian-In-Charge (VIC) for the cancellation of approval of food premises to export products to United States based on observations by inspection personnel of HACCP, sanitation, laboratory testing, or other non-compliances and for 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. Two types of certificates are used: fresh meat and meat by-product. 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 products 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 Radio analytical Laboratory

In addition to eight labs referenced above, Hungary has a National Reference Laboratory in Budapest. This reference laboratory conducts analyses for both micro and chemical samples. The eight government laboratories cited above are 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 was 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 duties, conducts annual reviews and audits of the laboratories, which are responsible for testing of product destined for export to the United States. The CCA's 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's audit reports and its related follow-up reviews. No concerns arose as the result of these reviews. Under the Act of the Central Budget, the NEBIH funds the laboratory analysis, while the county/district funds the inspection personnel salaries. The negative laboratory test results are sent to the in-plant inspection officials and county office. Any positive laboratory test results are sent to the in-plant government veterinarian, county office, and the NEBIH.

The CCA's authority to enforce inspection laws is specified in Hungary's Act 48 of 2008 and Government Decree 328/2010. 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 four 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 three 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, Sanitation Performance Standards (SPS), or slaughter activities were observed.

In all locations, the supervisory reviews were conducted using a standard form that consists of a checklist. This form evaluates 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*). Government and establishment officials also test listeria monocytogenes (Lm) and Salmonella for RTE product. Additionally, the form consists of questions that evaluate the knowledge, skills, and abilities of inspection personnel to conduct assigned responsibilities at United States eligible establishments. The periodic supervisory review reports are sent to the audited establishment's management and the related county office. The 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 United States 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 establishment's verified sanitary conditions, including the evaluation of written sanitation programs, monitoring, and implementation of sanitation procedures, record reviews, 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 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.

In conclusion, FSIS observation of inspection program activities of Hungary's meat inspection system confirms that the CCA continues to have administrative controls to support its inspection system, and that it is consistently enforcing applicable regulatory requirements equivalent to those governing the United States' system of meat inspection. The auditor confirmed that no changes in the inspection system have occurred since the last audit of Hungary conducted in 2013. New changes in FSIS regulations are transmitted electronically from the headquarters to the state and county offices and then to the in-plant inspection personnel. The review and analysis of all documents, as well as on-site observations and interviews conducted by the FSIS auditor, establish that NEBIH continues to have the ability to meet and effectively implement its standards and duties.

#### **IV. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)**

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 humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to United States 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 the official inspection and verification activities were in accordance with the responses in the SRT and supporting documentation.

During the FSIS audit of CCA headquarters, the 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, including The Food Act: Act XLVI of 2008 on the food chain and Government Decree No 22/2012 (II. 29) on the National Food Chain Safety Office. There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the CCA.

The auditor confirmed that the CCA provided the county and establishment inspection offices with the appropriate regulatory authority and guidance to enforce requirements for humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to United States eligible establishments.

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.

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. During the on-site audit of one swine-processing establishment, the FSIS auditor reviewed and observed the in-plant inspection verification activities for RTE sampling and testing in samples for *Lm* and *Salmonella*.

At the slaughter establishments, the FSIS auditor verified that in-plant VIC conducted ante-mortem inspection on the day of slaughter by reviewing the incoming registration and owner's identification documents and 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 were 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 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.

The FSIS auditor assessed post-mortem inspection examinations through on-site audit, record review, interviews, and observations of inspection activities against EU Regulation No. 854/2004-Post-mortem 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. Line synchronization of carcasses and viscera was properly maintained. These actions were in accordance with Hungary's adoption of (EU) Annex I, Section I, Chapter II B (Ante-mortem) and D (Post-mortem), "Regulation No. 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"- ante and 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 that daily inspection verification activities are appropriately conducted. These daily verification activities include 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 United States 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. in addition, of the EU Regulation No 854/2004 EC/as well as in paragraph 35 (3) (c) of Act 46 of 2008 which refers to 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. 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.

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, one processing establishment audited, and the county veterinary supervisors employed by NEBIH conducted the cold storage supervisory reviews quarterly. An action plan was written to address needed corrective actions after the quarterly review. The VIC verifies the corrective actions and performs a follow-up within one month on the proffered corrective actions. HQ performs supervisory reviews every six months.

FSIS auditor 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 the monitoring and verification records generated by establishment and in-plant inspection personnel at all audited establishments. All audited documents were in order.

Hungary's meat inspection system continues to have both legal authority and a very well documented regulatory framework to implement requirements equivalent to those governing the United States system of meat inspection. All audited equivalency requirements were fully implemented by the Hungarian CCA.

## **V. 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). During the document review and before 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 four audited establishments.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the four 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 and his supervisor conducting pre-operational sanitation verification of slaughter and fabrication areas of the establishment. The in-plant hands-on verification procedures started after the establishment personnel had conducted their pre-operational sanitation and had determined that 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 that FSIS has determined to be equivalent to those of the United States (9 CFR 416.13 (a) (“Implementation of SOPs”).

The FSIS auditor followed the off-line inspectors and observed inspection verification of operational sanitation procedures at all four 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 an inspector. The auditor noted that the inspection and establishment records mimic 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 FSIS auditor assessed the NEBIH’s ability to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included a review of the official inspection records, the establishment’s sanitation monitoring records, documented corrective actions, and assessment of the actual sanitary conditions in the production area. The 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 for development and implementation of SSOPs by adopting 9 CFR 416. This document requiring SSOP was published in “Horizontal Guide for checking specific export requirements,” issued in June 2008 by the CCA. Local and county officials can find this guide through the intranet system of the CCA. Additionally, the FSIS auditor verified that the inspection system is ensuring sanitary handling of products.

The FSIS auditor verified that the NEBIH had implemented corrective action plans to previous audit findings and several SPS deficiencies identified during this audit. In-plant veterinary officials and state supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions.

## **VI. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) 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 auditor visited the CCA's headquarters, one NEBIH county office (Veszprem), three establishments and one cold storage establishment to determine whether the NEBIH inspection offices maintained effective government verification of 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 United States 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 United States model of HACCP.

The FSIS auditor verified through record reviews and observations that the in-plant inspection personnel at the certified establishments conducted once per shift, daily verification, of HACCP plans in accordance with methodology described in the CCA's Official Guide, 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. When a case of non-compliance was recorded, the auditor found that proper corrective action was performed. At both establishments, inspection monitoring and verification records documented some deviations from the critical limits of some CCPs. 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.

The United States HACCP requirement that United States eligible establishments implement preventive measures to deviations 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. The FSIS auditor observed no deviations from the critical limits. 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 verifies that there is compliance with those requirements.

## **VII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING 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 the 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 United States 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 control 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 the 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 2015 laboratory audit report: Annual Monitoring Audit of Central Residue/Toxicology Laboratory in Budapest. 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 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 laboratory non-compliance.

The 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 under refrigeration. 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 participate in both intra- and inter-laboratory proficiency testing. International proficiency 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 meet the core equivalence requirements for this component. Both the document analysis of the National Residue Control Program and on-site audit verification activities show that Hungary's meat inspection system has regulatory requirements designed and administered in accordance with requirements and standards determined to be equivalent by FSIS. No residue POE violations have been observed for a period of 3 years.

## **VIII. COMPONENT SIX: GOVERNMENT 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*," which was 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 *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 (e.g., *Lm*, *Salmonella* spp., and *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 three processing establishments audited. The auditor visited one microbiological laboratory in Budapest.

The CCA has a *Salmonella* testing program for carcass sampling that meets the 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 days 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 of the issue, takes proper corrective actions and implements 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/Enterobacteriaceae* testing program in chilled swine carcasses. The testing program complies with FSIS equivalence criteria. While on-site at one slaughter establishment, 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 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' equivalence criteria for RTE *Lm* control programs require that the CCA verify the implementation and effectiveness of control measures in each establishment certified to 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 the 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 observations, interviews and review of inspection documents at the CCA headquarters in Budapest, Veszprem County Office, three 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 equivalence plan.
- The methods utilized by the CCA to determine whether *Lm* is present in RTE product is in accordance with "FSIS Method MLG 8.07," and for *Salmonella* detection, the CCA uses 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 export to the United States, as required for equivalence. Additionally, when product is prepared for United States 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 and procedures used for sample collection, sample registration and handling, sampling frequency, timely analysis, calibration of equipment, internal audits (intra and inter laboratory), acceptable methods, traceability of samples and sample analysis, ISO 17025 requirements, and verification of corrective actions for non-compliances. The FSIS auditor found no basis for concern after observing the CCA's system and reviewing the most recent annual laboratory audit report.

After observing the laboratory conduct the sample analysis and documentation of the process, the auditor concluded that the CCA performs proper oversight of the micro laboratory and consistently enforces the applicable requirements for microbiology testing program. There were no microbiological POE violations observed over the last 3 years by FSIS.

## **IX. CONCLUSIONS AND NEXT STEPS**

The audit was designed to determine the equivalence of Hungary's meat inspection system by examining not heat-treated (shelf stable) smoked and fully cooked-not shelf stable, heat-treated, not fully cooked (non-shelf stable) products in two slaughter/processing establishments, one processing establishment, and one cold storage establishment. The audit focused on verification of six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the April 2013 FSIS audit 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, one meat processing establishment producing RTE product, and one cold storage establishment. Currently, Hungary has five certified establishments approved for United States export, but only three establishments export directly to the United States. These establishments export cured meat products, including smoked salami, bacon, and ham.

- Several SPS non-compliances were identified and reported as corrected by the CCA to the auditor.

An examination of POE data between April 1, 2014, and March 31, 2015, showed that 95 % of the total of meat products imported into the United States was produced from two establishments that were re-inspected. A total of 1,176,873 pounds of meat products were shipped to the United States, and no food safety violations were found. The FSIS audit found that Hungary's inspection system is maintaining the core requirements and its equivalence based on POE violation results and audit observations.

## Appendices

## Appendix A: Individual Foreign Establishment Audit Checklist

Appendix B: Hungary's Response to Draft Final Audit Report – None received

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PAPAI HUS 1913 Elemiszeripari Feldolgozo PAPA HU-6 Hungary	2. AUDIT DATE June 19, 2015	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Date: June 19, 2015 Est #: H-6 (Papa, [S/P]) (Papa, Hungary)

45/51/56 During the pre-operational, on-site tour, the FSIS auditor observed that the conveyor belt had deep cuts in some areas and it was damaged on the side in other areas of the belt in the boning room which might prevent proper cleaning of the belt. The CCA representatives took immediate corrective action and establishment management implemented the inspection service instruction by removing and replacing all damaged conveyor belts. EU Reg. 853/2004, Annex III, 1(a).

46/51 During the on-site operational tour, the FSIS auditor observed condensation over the offal cooler product way. This deficiency was corrected immediately by removing the overhead condensation from the refrigeration unit and by mechanical adjustment of the unit by the establishment management EU Reg. 853/2004, Annex III, 1(a).

61. NAME OF AUDITOR  
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PICK SZEGED Zrt, H-6725 Szeged, Szabadkai ut 18. Szeged, Hungary	2. AUDIT DATE June 23,	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			



## 60. Observation of the Establishment

Date: June 23, 2015 Est #: HU-7 (Pick. [S/P]) (Szeged, Hungary)

45/51 During the operational sanitation, on-site audit, the FSIS auditor observed that chain support for moving carcasses to the chiller was found rusty. This non-compliance was corrected immediately by the establishment management and verified by inspection service before the departure of the auditor from the establishment. EU Reg. 853/2004, Chapter V, 2.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PICK SZEGED ZRT 7345 Alsomocsoladi ut 2. Alsomocsolad Hungary	2. AUDIT DATE June 24, 2015	3. ESTABLISHMENT NO. 86 EK	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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Date: June 24, 2015 Est #: 86 EK (Pick. [P]) (Alsomocsolad, Hungary)

*There are no significant findings to report concerning this establishment and the government oversight verification.*

61. NAME OF AUDITOR  
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Dunakeszi Hutohaz KFT-Cold Storage 2120 Tozegtavi u. 1. Dunakeszi Hungary	2. AUDIT DATE June 28, 2015	3. ESTABLISHMENT NO. HU 55 EK	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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

Date: June 28, 2015 Est #: 55 EK [CS]) (Dunakeszi Hutohaz-Cold Storage, Hungary)

*There are no significant findings to report concerning this establishment and the government oversight verification.*

61. NAME OF AUDITOR  
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE