United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

MAY 17 2018

Dr. Lajos Bognar
State Secretary
Ministry of Agriculture
Food Chain Control and Agricultural Administration
Kossuth ter 11
H-1055 Budapest, Hungary

Dear Dr. Bognar,

The Food Safety and Inspection Service (FSIS) conducted an ongoing on-site equivalence verification audit of Hungary's pork products inspection system from November 27 through December 15, 2017. Enclosed is a copy of the final audit report. The comments received from the Government of Hungary are included as an attachment to the report.

In addition, FSIS acknowledges that the National Food Chain Safety Office (NFCSO) has provided documentation to address the findings noted during the on-site audit. FSIS is in the process of evaluating your response, and may be requesting additional information regarding Hungary's inspection procedures related to verification of establishment HACCP systems and control of *Listeria monocytogenes* in the post-lethality environment. Once complete, FSIS will notify you as to whether Hungary's pork products inspection system remains equivalent to that of the United States.

For any questions regarding the FSIS audit report, please contact us at (202) 708-9543, or by electronic mail at internationalcoordination@fsis.usda.gov.

Sincerely,

Todd Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

HUNGARY

NOVEMBER 27 TO DECEMBER 15, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

April 30, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from November 27 to December 15, 2017. The purpose of the audit was to determine whether Hungary's food safety system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Although eligible to export raw pork, Hungary currently exports only heat treated-not fully cooked-not shelf stable, ready-to-eat (RTE) fully cooked, RTE fermented, and RTE dried pork products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors identified the following significant audit findings. As a result of these audit findings, FSIS immediately began to increase point of entry (POE) sampling of pork product exported to the United States. The increased POE sampling will continue until the concerns related to these findings are resolved. In addition, FSIS requested that the Central Competent Authority (CCA) take immediate corrective actions to address these findings.

Government Oversight (e.g., Organization and Administration)

- Inspection personnel did not consistently document noncompliances identified during regular onsite verification activities and issued only verbal instructions to correct any identified deficiencies.
- The CCA has not provided adequate training to inspection personnel regarding basic HACCP system requirements; control of *Listeria monocytogenes* (*Lm*) in the post-lethality environment, and lethality in RTE fermented and dried products.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The CCA did not ensure that establishments maintained adequate hazard analyses, as evidenced by establishments' failures to identify all hazards, to include prerequisite programs, and to reference the supporting records.
- The CCA did not ensure that establishments maintained adequate HACCP plans, as evidenced by establishments' failures to identify specific frequencies of verification activities, to describe all aspects of corrective actions, and to maintain supporting evidence for the selection of critical control points.

Government Chemical Residue Testing Programs

- The online reporting system for entering laboratory samples does not detect omissions such as missing animal identification numbers on residue sample forms.

Government Microbiological Testing Programs

- The CCA's current RTE verification sampling program does not include on-going verification sampling of food contact surfaces and environmental surfaces (non-food contact) for *Lm*.
- The CCA did not document parameters associated with the testing methods for *Lm* and *Salmonella*, and did not implement the *Lm* testing method as prescribed.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Hungary's food safety system from November 27 to December 15, 2017. The audit began with an entrance meeting held on November 27, 2017 in Budapest, Hungary, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the National Food Chain Safety Office (NFCSO).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Hungary is eligible to export raw, heat treated-not fully cooked-not shelf stable, ready-to-eat (RTE) fully cooked, RTE fermented, and RTE dried pork products to the United States. The USDA's Animal and Plant Health Inspection Service recognizes Hungary as low risk for classical swine fever and free of foot and mouth disease, and swine vesicular disease with restrictions.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA, county offices, district offices, and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters, two county, one district, and six local inspection offices. The FSIS auditors evaluated the implementation of the control systems in place to ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors visited all six establishments certified as eligible to export to the United States including one slaughter and processing establishment producing RTE fully-cooked pork, one processing establishment producing RTE fermented pork, one processing establishment producing RTE dried pork, one processing establishment producing heat treated-not ready to eat-not shelf stable processed pork, and two cold storage establishments. During the establishment

visits the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, the FSIS auditors visited one microbiological laboratory and one chemical residue laboratory to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• National Food Chain Safety Office, Budapest
	County	2	• Bács-Kiskun County Government Office, Bacs-Kiskun • Veszprem County Government Office, Veszprem
	District	1	• District Government Office of Kiskunfélegyháza Food Chain Safety and Animal Health Unit, Bacs-Kiskun
Laboratories		2	• National Food Microbiological Reference Laboratory, Budapest • National Food Toxicological Reference Laboratory, Budapest
Pork slaughter and processing establishment		1	• Establishment HU 6 EK, Papa
Pork processing establishments		3	• Establishment HU 7 EK, Szeged • Establishment HU 22 EK, Pecs • Establishment HU 365 EK, Alsomocsolad
Cold storage facilities		2	• Establishment HU 55 EK, Dunakeszi • Establishment HU 553 EK, Pecs

The audit was performed to verify whether the country's food safety system was equivalent to FSIS' system in regards to specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of Hungary's inspection system for slaughter and processed meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement; and includes the following:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;

- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

Hungary currently exports NRTE otherwise processed, RTE fully cooked, RTE fermented, and RTE dried pork products to the United States. From August 1, 2014 to July 31, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,960,175 pounds of pork exported by Hungary to the United States. Of that amount, additional types of inspection were performed on 627,879 pounds, including testing for residues, *Salmonella* and *Listeria monocytogenes* (*Lm*). No products were rejected for issues related to public health or other reasons.

The previous FSIS audit in 2015 identified isolated findings related to the Government Sanitation component. At three establishments, during the previous audit, the FSIS auditor identified the presence of condensation on an overhead structure, a damaged conveyor belt during pre-operational inspection, and a rusted chain support for moving carcasses in a carcass chiller. The FSIS auditors verified that all previously reported findings had been adequately addressed.

The evaluation of all six equivalence components included a review and analysis of documentation submitted by the CCA as support for the responses provided in the SRT. The FSIS onsite audit included record reviews, interviews, and observations made by the FSIS auditors. The FSIS final audit reports for Hungary's food safety system are available on the FSIS Web site at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative and technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States at least once per shift at processing establishments and on the line during all slaughter operations.

The Ministry of Agriculture (MA) is responsible for the oversight of food and veterinary controls at the Ministry level. The Chief Veterinary Officer (CVO) is appointed by the Minister of Agriculture and is the most senior level for veterinary and food inspection activities. The

National Food Chain Safety Office (NFCSO) serves as the CCA and operates under the direction and supervision of the MA. The NFCSO, Food Chain Control and Animal Health is managed by the Deputy CVO or President, who is appointed by the CVO. The NFCSO is responsible for meat inspection at establishments certified as eligible to export to the United States.

The NFCSO represents the first level of legal authority of the inspection system and provides overall regulatory oversight to the establishments certified as eligible to export pork products to the United States. The Department of Food Chain Safety of the County Government Offices (CGO) represents the second level of inspection. In January 2016, the responsibilities of directly overseeing the establishments certified to export to the United States were delegated from the CGOs to the District Government Offices (DGO). The Food Chain Safety and Animal Health Unit of the DGO represents the third (i.e., local) level of inspection. The DGOs control establishments certified to export to the United States within their jurisdictions and are headed by Chief District Veterinarians.

The FSIS auditors performed onsite observations and reviewed records maintained by inspection personnel at headquarters, CGOs, DGOs, and inspection offices within establishments certified to export to the United States. Officials use the authority of the laws of Hungary to enforce the rules of the meat inspection system, identify and document noncompliances, and verify the adequacy of corrective actions and preventive measures. The enforcement strategies in place are based on Regulation (EC) No. 882/2004 and under Article 57 of the national law *Act 46 of 2008,* which authorizes the CCA to approve and certify establishments as eligible to export to the United States. *Act 46 of 2008* further provides the CCA the legal authority to conduct inspection activities in establishments certified to export to the United States and assess penalties for violations of food safety laws. The DGOs, CGOs, and CCA have the authority to suspend or withdraw certification of establishments certified to export to the United States.

The CCA has adopted the definition of adulterated product that may not be placed on the market, as it is defined under Article 14 of Regulation (EC) No. 178/2002, as unsafe food that is injurious to health and unfit for human consumption. Additionally, misbranded product is addressed under Article 8 of Regulation (EC) No. 178/2002, which prohibits practices that may mislead the consumer, and fraudulent or deceptive practices. The FSIS auditors verified that there have not been any product recalls from establishments certified as eligible to export to the United States since the last audit in 2015. The FSIS auditors verified that the NFCSO prepares annual inspection plans and reviewed the recent reports for establishments certified to export to the United States.

The FSIS auditors verified the approval procedures for establishments to be certified as eligible to export to the United States and reviewed the documented assessments of the new establishments certified to export to the United States. Establishments that intend to export to the United States must submit an application to the CGO. The CGO then conducts the initial export approval review through a comprehensive establishment audit, which consists of a review of the establishment's documentation including HACCP, sanitation, and sampling documents as well as onsite visits to the establishment to verify that all regulatory requirements specific to an importing country have been met. If approved, county officials inform the NFCSO, which then

conducts an audit of the establishment. The NFCSO has the sole authority to grant final certification of a new establishment or to permit an existing establishment certified to export to the United States to maintain its eligibility to export to the United States.

FSIS' review of Hungary's inspection activities 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 work instructions in its *Manual Horizontal Audit Plans Related to the Special Export Conditions*, which outlines the United States export requirements to establishments and inspection personnel including zero tolerance for *Lm* and *Salmonella* in RTE pork products, generic *E. coli* sampling, *Salmonella* carcass sampling, and product labeling.

The CCA also issued the *Official Guide*, which includes instructions to inspection personnel at slaughter and processing establishments that implement EC regulations. The CCA also issued *The Application of the Regulatory Measures in Facilities Under the Scope of HACCP System Requirements,* which includes instructions and checklists for inspection personnel to verify the United States export requirements.

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. The FSIS auditors confirmed that the NFCSO has the authority to take enforcement actions and impose fines. However, there have been no enforcement actions taken or fines imposed on establishments certified to export to the United States since the last audit.

Official verification and inspection activities are conducted at all establishments certified to export to the United States in accordance with instructions disseminated from the NFCSO to the field via email, telephone, and hard copy. These programs and manuals contain procedures to assist official personnel in uniformly assessing the adequacy of equivalent 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 auditors reviewed daily inspection documentation and verified that inspection personnel have the authority to take regulatory control action and issue noncompliance records. However, the FSIS auditors identified the following finding:

- In two of the six establishments certified to export to the United States, inspection personnel were not consistently documenting noncompliances identified during regular onsite verification activities, issuing only verbal instruction to correct any identified deficiencies. Interviews with inspection personnel indicated that consistent documentation of noncompliances occurred only in conjunction with monthly supervisory reviews led by members of the DGO.

The CCA is implementing the document *Manual Horizontal Audit Plans Related to the Special Export Conditions* that requires source products can only originate from establishments certified to export to the United States, which is verified by inspection personnel. The FSIS auditors verified through production records that all source product originated from establishments

certified to export to the United States from countries that are eligible to export the applicable product to the United States. Hungary is currently importing source material from Austria and Italy from establishments certified to export to the United States. The FSIS auditors observed that products destined for United States export are kept separate from domestic products at each establishment.

The FSIS auditors verified that the NFCSO has the ability to track 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. The FSIS auditors verified that export certificates and stamps are under the control of the inspection personnel. The NFCSO has controls in place to prevent the fraud or misuse of export health certificates.

The FSIS auditors verified that all government inspection personnel assigned to establishments certified to export to the United States are employees of the DGOs, who are paid directly by the government. This was verified through a review of employment contracts and employment records of employees assigned to establishments certified to export to the United States. Employees of the government are required to take civil service training covering conflict of interest. Performance evaluation of employees is required twice a year for civil servants under *Ministerial Decree 10/2013*. The DGOs are responsible for hiring and assigning qualified inspection personnel to establishments certified to export to the United States.

The FSIS auditors reviewed documentation to ascertain that the Official Veterinarians (OV) had the required veterinary degrees, and that Official Auxiliaries (OAs) had the required pre-employment training program and education. This documentation was reviewed for a sampling of individuals including both veterinarians and inspectors that are assigned to establishments certified to export to the United States. 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. OAs, in accordance with Regulation (EC) No. 854/2004, have inspection courses at the university or high school level as well as on-the-job training.

The FSIS auditors verified that the visited pork slaughter establishment was staffed with an appropriate number of inspection personnel to conduct post-mortem inspection for each carcass, accounting for line speed. The line speed was 160 carcasses per hour with four inspectors (1 head inspector, 2 viscera inspectors, and 1 carcass inspector). The processing establishments have the required number of inspection personnel to conduct once per shift inspection activities. The DGOs were maintaining procedures for relief assignment if there were absences of inspection personnel in slaughter and processing.

The FSIS auditors verified that the CCA maintains a communication system for FSIS requirements, which are transmitted electronically from the NFCSO to CGOs and DGOs via email and verbally by CCA officials. The NFCSO provides training to CGOs on a yearly basis on the subject of third countries' (including the United States) requirements for sanitation standard operating procedures (sanitation SOP), HACCP, generic *E. coli,* and *Salmonella,* and *Lm.* The FSIS auditors reviewed the recent trainings held by NFCSO and verified that training

records were maintained for the CGO employees in attendance. The CGO supervisors are also responsible for distributing the training materials to DGO employees that are assigned to establishments certified to export to the United States via email.

- The FSIS auditors verified that the DGO employees were provided with the training materials; however, the CCA did not provide adequate training to inspection personnel regarding the following areas of regulatory oversight:
  - Basic HACCP system requirements consistent with those in 9 CFR 417;
  - Control of *Lm* in the post-lethality environment; and
  - Lethality in RTE fermented and dried products.

The FSIS auditors verified that the methods of analysis used in official laboratories have been accredited by an international organization. In addition, NFCSO conducts annual audits to verify that laboratories are employing *FSIS Microbiology Laboratory Guidebook* (MLG) *8.10* method for analysis of *Lm* and the International Organization for Standardization (ISO) 6579:1998 method for analysis of *Salmonella* when sampling and analyzing pork products destined for export to the United States. The FSIS auditors verified that *Laboratory Quality Control Manual* and *Quality Assurance Handbooks* are being followed as required and the CCA is conducting annual audits of official laboratories.

The laboratories are accredited by "Nemzeti Akkreditaló Testület" (NAT) following the ISO 17025:2005 standard. The FSIS auditors reviewed results of proficiency testing being conducted at official laboratories and the qualifications and training of the laboratory personnel, which showed that the analysts met the qualification requirements and successfully passed the proficiency tests. The FSIS auditors confirmed that laboratory results are sent to NFCSO headquarters, CGOs, DGOs, and inspection personnel.

Hungary has a National Reference Laboratory in Budapest. This reference laboratory conducts official verification analyses of meat products for both microbiological and chemical residues. The CCA's annual laboratory audit report includes administrative and technical aspects of the analytical methodology, laboratory personnel qualifications and training, and maintenance of the laboratory equipment. The FSIS auditors reviewed the CCA's audit reports and its related follow-up reviews, which demonstrated that the CCA provides adequate technical support to the laboratories.

The audit determined that Hungary's government organizes and administers the country's meat inspection system, and that NFCSO officials enforce laws and regulations governing production and export of meat at establishments certified to export to the United States. The ongoing analysis of available data and audit verification activities indicate that the CCA has developed administrative procedures, but their implementation is not adequate. Weaknesses in its implementation of regulatory oversight included inadequate training of inspection personnel assigned to establishments certified to export to the United States and incomplete records of enforcement activities at establishments certified to export to the United States. The CCA committed to provide FSIS with corrective action plans, which will be verified once they are implemented.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety, and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; inspection at least once per shift during processing operations and on-line inspection during slaughter operations; and periodic supervisory visits to official establishments.

The FSIS auditors reviewed the slaughter practices at the visited establishments and determined that inspection personnel verify that humane handling and slaughter of livestock is conducted in accordance with European Union (EU) regulations. The CCA issued *Decree No. 140/2012 (XII.22)* and *Control System for Animal Welfare* as the implementing documents for Regulation (EC) No. 1099/2009, which describes the responsibilities and official controls for humane handling.

The FSIS auditors verified that ante-mortem inspection is being conducted in accordance with Regulation (EC) No. 854/2004, Annex I Section I Chapter I, II and IV (A) to meet the requirements for ante-mortem inspection of livestock, which requires the OV to carry out an ante-mortem inspection of all animals before slaughter within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter. The *Official Guide*, issued by the CCA provides additional instructions to implement ante-mortem inspection as required under the above-mentioned EC regulation. The FSIS auditors verified that this was being conducted as prescribed on the day of slaughter through observation of ante-mortem inspection and a review of ante-mortem condemnation records. Additionally, the OVs were reviewing the incoming registration and owner's identification documents and animal identification documents. In accordance with procedures and requirements, the OVs 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. The audited slaughter establishment had a designated observation pen for further examination of suspect animals.

The FSIS auditors verified that government inspection personnel were performing on-line post-mortem inspection of each and every carcass and that it was conducted in accordance with Regulation (EC) Nos. 853/2004 and 854/2004 to meet the requirements of post-mortem inspection. Hungary additionally issued the *Official Guide*, which serves as an implementing document providing guidance on post-mortem inspection including zero tolerance verification of feces, ingesta, and milk on each carcass. Post-mortem inspection is required to be performed by government inspection personnel at the time of slaughter. The FSIS auditors verified that this is occurring through observation of inspection personnel conducting on-line post-mortem inspection of each carcass and through a review of condemnation records.

The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. Both OVs and OAs were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditors observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, palpation of required organs, and lymph nodes were made. Line synchronization of carcasses and viscera was properly maintained. The design of the post-mortem inspection stations including proper lighting and the appropriate number of on-line inspectors consistent with the requirements of 9 CFR 310.1.

The CCA issued the *Manual Horizontal Audit Plans Related to the Special Export Conditions,* which requires the presence of an OV, at least once per shift, during the manufacturing of products for export to the United States, and that this inspection must be documented. The FSIS auditors reviewed the daily inspection records and verified that this is occurring as prescribed. The FSIS auditors verified that separation is maintained between product destined for export to the United States and domestic product. This is maintained through either separate production days or separate production lines and designated storage areas that are used for these products. The CCA is ensuring that only pork products that are currently not restricted for export to the United States by monitoring the USDA's Animal and Plant Health Inspection Service website, and verifying restrictions under 9 CFR 94.1 prior to signing export certificates. Export requirements including disease restrictions are listed on the NFCSO website.

Supervisory reviews at establishments certified to export to the United States are conducted by the NFCSO every six months, by the CGOs every three months, and by the DGOs on a monthly basis. The FSIS auditors reviewed the most recent supervisory visits and determined that supervisory visits are conducted at the prescribed frequencies by the NFCSO, CGOs, and DGOs. Supervisory reviews were conducted using a standard checklist form. This form evaluates the adequacy of the establishment's food safety system, including items related to inspection verification of Sanitation Performance Standard (SPS) elements, sanitation SOP, HACCP, and microbiological control for generic *E. coli, Salmonella,* and *Lm.* Additionally, the form contains questions that evaluate the knowledge, skills, and abilities of inspection personnel that are assigned to establishments certified to export to the United States. Supervisory reviews additionally consist of evaluating the performance of OVs and OAs. The periodic supervisory review reports are sent to the audited establishment's management and the related DGOs. If deficiencies are identified, an action plan is written to address needed corrective actions after the supervisory review. The OV is responsible for verification of corrective actions resulting from the review. The DGO is responsible for analyzing the results of the review.

The FSIS auditors 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 consisted of a direct observation of the establishment monitoring of HACCP, sanitation SOP, and Sanitation Performance Standard (SPS) as well as a record review of establishments' records, including HACCP, sanitation SOP and SPS, generic *E. coli, Salmonella,* and *Lm* sampling records. The FSIS auditors also verified that the inspection personnel are also responsible for reviewing product formulation and label verification as part of their daily inspection. The FSIS auditors verified

that control over condemned materials is maintained through application of Regulation (EC) Nos. 1069/2009 and 142/2011, including appropriate identification in accordance with the categories described therein; segregation in specially-marked or otherwise secure containers, and final documented disposal of these materials at nearby rendering facilities.

Hungary's meat inspection system continues to maintain the legal authority and a regulatory framework, which as described, is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at the four audited establishments. In one of the establishments, the FSIS auditors verified the adequacy of pre-operational inspection by observing the OV conducting pre-operational sanitation verification of slaughter and fabrication areas of the establishment. The hands-on verification procedures started after the establishment personnel had conducted their pre-operational sanitation and had determined that the facility was ready for pre-operational sanitation verification activities. The NFCSO has authority for official control over establishment construction, facilities, and equipment in accordance with *Act 46 of 2008, paragraph 35 (3) (c),* which stipulates food hygiene and its official control.

The FSIS auditors followed the off-line inspectors and observed inspection verification of operational sanitation procedures at all audited establishments. These verification activities included direct observation of operations and review of establishment records. The FSIS auditors also reviewed the establishment's sanitation monitoring and the corresponding government verification records and noted that the inspection and establishment records correspond with the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. The establishment employees specified as being responsible for the implementation and monitoring of the sanitation SOP procedures correctly authenticated these records with initials or signatures and the date.

The FSIS auditors assessed the ability of inspection personnel 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 inspection personnel are ensuring that the requirements of Article 4.2 of Regulation (EC) No. 854/2004 are met and 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 sanitation SOPs consistent with 9 CFR 416. This document requiring sanitation SOPs was published in *The Application of the Regulatory Measures in Facilities under the Scope of HACCP System Requirements,* which describes and provides a checklist for

Sanitation SOP requirements consistent with 9 CFR 416. Inspection personnel can find this guide through the intranet system of the CCA.

The FSIS auditors verified that the inspection system is ensuring sanitary handling of products. The CCA exercises its legal authority to require that the Establishments certified to export to the United States develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or the creation of insanitary conditions. The in-plant inspection personnel at all audited establishments' 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, wastewater, pest control, cleaning and sanitization, hygiene, hygienic habits and workers' health; and operational sanitary procedures.

The CCA's inspection system for pork continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The CCA is utilizing *The Application of the Regulatory Measures in Facilities Under the Scope of HACCP System Requirements*, which provides instructions consistent with the United States HACCP requirements, and the *Official Guide*, which provides procedures for the oversight of HACCP-based procedures. The CCA requires each establishment that is certified to export to the United States to develop, implement, and maintain a HACCP system.

The FSIS auditors conducted an onsite review of the establishments' HACCP systems, including flow charts, hazard analyses, HACCP plans, and related HACCP records. The FSIS auditors verified implementation of government verification of HACCP systems in the audited establishments. The FSIS auditors conducted an onsite observation and review of the zero tolerance (feces, ingesta, and milk) control records in the audited porcine slaughter establishment. The FSIS auditors reviewed the OV's associated zero tolerance verification records, for which no failures were identified. The FSIS auditors also verified the physical critical control point (CCP) location by observing the OV conducting HACCP hands-on verification activities.

However, the FSIS auditors identified noncompliance with basic HACCP requirements that government verification failed to identify at four of the six audited establishments, including:

- Deficiencies related to hazard analysis requirements:

- Failure to identify the pre-requisite programs used to control hazards related to the production of RTE products, e.g., microbiological testing of raw meat ingredients at the receiving raw products step.
- Failure to list the documentation used to support the use of prerequisite programs supporting documents maintained by the facility demonstrating why hazards are not reasonably likely to occur during the production of RTE products, e.g., microbiological challenge studies.
- Failure to identify chemical hazards at process steps where chemicals were being introduced.
- Failure to identify *Lm* as a potential hazard at process steps in the post-lethality environment for RTE post-lethality exposed (PLE) dried and fermented products.

- Deficiencies related to the contents of the HACCP plan were identified at four of the six audited establishments:
  - Failure to maintain documentation associated with the selection of the critical limits of the chilling CCP for RTE ham products.
  - Failure to list the specific frequencies of direct observation of monitoring and records review.
  - Failure to list the specific frequencies for calibration of process monitoring instruments.
  - Failure to list all corrective actions in the HACCP plan.
  - Failure to develop supportable *Lm* verification programs which include sampling of primary food contact surfaces (FCSs). The establishments did not consider product coming into direct contact with a FCS that is contaminated with *Lm* to be adulterated within the context of their sampling programs, although there had been no FCS positives identified in recent history.

The FSIS auditors determined that the CCA requires operators of establishments certified as eligible to export to the United States to develop, implement, and maintain HACCP systems. However, the audit findings listed above demonstrate that the CCA's inspection system did not effectively verify the adequacy of design and implementation of HACCP systems. The CCA committed to provide FSIS with corrective action plans, which will be verified once they are implemented.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

FSIS based its verification of Hungary's residue control program on information contained in EC Directive 96/23, *Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products;* in association with Hungary's current National Residue Program (NRP) sampling plan and previous years (2015-2016) testing results, for which updated versions were provided to the FSIS auditors while onsite. The FSIS auditors also conducted an onsite audit of

one residue laboratory that performs residue analysis on products exported to the United States. No violations for residues were identified at United States POE since the last FSIS audit in 2015.

The FSIS auditors verified that the NFCSO continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of swine slaughtered for human consumption. This regulatory task is accomplished with the participation of the NFCSO regional and reference laboratory network, and technical teams from the Directorates for Veterinary Medicinal Products and Food and Feed Safety. These directorates work under the Deputy President for Food Chain Control and Animal Health, who reports directly to the NFCSO's Deputy Chief Veterinary Officer.

The FSIS auditors noted that the NRP covers animal species slaughtered for the production of meat for domestic and international markets. In accordance with EC Directive 96/23, the design of the sampling protocols has taken the following into consideration: the registered use of a chemical compound of interest; the likelihood of a residue occurring in animal tissues; the extent and pattern of use of the compound; incentives for misuse; known persistence of the compound in the environment; past monitoring results; and requirements of importing countries.

The NRP is developed at the central level, after which it is the responsibility of each CGO to prepare individual sampling schedules that are distributed to official veterinarians for the random sampling of tissues. Sampling, handling, and transporting of samples within the field is done in accordance with instructions contained in government issuance ME-17, *Treatment of Samples,* by the OV. While the routine monitoring program does not require holding product until sample results are received, product is held and precluded from export during any subsequent follow-up sampling that occurs as part of an initial violative result. This follow-up sampling is until the CCA's investigation into the cause of the violation is complete, and serves as an additional mechanism to ensure that no further adulterated product enters commerce. Any carcasses or portions thereof, presenting violative results are subject to recall (including those identified during routine monitoring).

During the evaluation of ante-mortem inspection at one swine slaughter establishment, the FSIS auditors observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. A review of the sampling records maintained at inspection offices indicated that the 2017 sampling program was being adhered to as scheduled.

Procedures followed in case of noncompliant results are included in Hungary's *Guidance for Authorities and Proceedings for Residue Toxicology*. If a maximum residue level is exceeded or there is suspicion of illegal treatment, the laboratory immediately informs the relevant CGO, the OV who performed the sampling, and NFCSO headquarters. In the case of suspicion of illegal treatment, the authority carries out an investigation of the source of substances or products concerned at the stage of manufacture, handling, storage, transport, administration, distribution,

or sale. All further movement of livestock from the farm of origin is restricted, and follow-up sampling conducted by the OV.

The FSIS auditors' review of testing results indicated that there had been no violative results for swine in the last year. In addition, an evaluation of documentation associated with a violation in equine meat (a species not eligible to export to the United States) indicated that procedures for addressing residue violations in livestock were implemented as intended.

The Toxicological National Reference Library serves as the principal laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory is ISO 17025:2005 accredited by the NAT on a four-year basis (last accredited in 2016). In addition, the NFCSO conducts internal annual audits of this laboratory. The laboratory maintains a web-based system to ensure accurate tracking and reporting of all samples received, and employs validated methods of analysis. This includes a recently validated (2016) multi-residue method for the analysis of over 50 veterinary drugs.

During the audit of this laboratory, FSIS reviewed the training records and certifications associated with the qualifications of the analysts. The documents reviewed demonstrated that analysts had successfully participated in intra and inter-laboratory evaluations administered by the laboratory manager and accrediting bodies. Furthermore, records and past internal laboratory audit reports demonstrate that laboratory managers readily respond to correct non-conformities identified during internal and external audits. The documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analyses within their accreditation scope.

- While reviewing the laboratory's web-based system for the traceability of samples, the FSIS auditors identified an instance where the animal identification number was not included on the sample submission form. Although the sample was not directly involved in United States export, this system is used for all residue sampling, including sampling of product destined for export to the United States. This finding indicates weakness in the system's design as it relates to data entry as well as review of documentation during sample receipt and audits of the quality management system.

The result of the onsite audit activities indicate that Hungary continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in pork products destined for export to the United States. However, the audit finding listed above demonstrates that the CCA's inspection system did not effectively verify the adequacy of system's design for data entry, sample receipt, and audits of the quality management system. The CCA committed to provide FSIS with corrective action plans, which will be verified once they are implemented.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing

programs to ensure that meat products produced for export to the United States are safe and wholesome.

The CCA has outlined supplemental microbiological testing requirements for export to the United States in its *Manual of Horizontal Audit Plans Related to the Special Export Conditions* in addition to the implementation of Regulation (EC) No. 2073/2005. This document includes the United States export requirements to establishments and inspection personnel including zero tolerance for *Lm* and *Salmonella* in RTE pork products, generic *E. coli* sampling, *Salmonella* carcass sampling, and product labeling, as well as the testing of RTE products for *Lm* and *Salmonella*. More detailed instruction regarding generic *E. coli* and *Salmonella* on swine carcasses is included in the CCA's *Application of the Regulatory Measures in Facilities under the Scope of HACCP System Requirements*.

The FSIS auditors accompanied and observed the in-plant inspection verification activities for *Salmonella,* and verification of establishment generic *E. coli* sample collection in one swine slaughter establishment. In addition, the FSIS auditors observed and verified the implementation of the government sampling program for *Lm* in three processing establishments. One government microbiological laboratory was audited.

The CCA has a *Salmonella* testing program for carcass sampling which is conducted by the OV that is consistent with 9 CFR 310.25(b). The CCA requires that one *Salmonella* set be scheduled by daily collection of one sample by a government inspector 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 the standard (c). The CCA's *Salmonella* performance standard for swine ($n = 55$, $c \leq 6$) is the same as FSIS's codified standards.

The CCA conducts verification activities that monitor an establishment's generic *E. coli* testing program in chilled swine carcasses. While onsite at one slaughter establishment, the FSIS auditors 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 establishment 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 onsite audits or noted in the past six months of documents reviewed.

The FSIS auditors evaluated the official microbiological sampling and testing program for *Lm* and *Salmonella* in RTE meat products and food contact surfaces (FCS) for *Lm*.

- The CCA's current RTE verification sampling program does not include on-going verification sampling of FCS and non-food contact environmental surfaces. Furthermore, once developed, the CCA will need to include clear instruction within its FCS testing program that identifies that all RTE pork products coming into direct contact with an FCS

that is tested and found to be contaminated with *Lm* is considered to be adulterated and ineligible for export to the United States.

The National Microbiological Reference Laboratory serves as the official laboratory conducting analyses of government samples for the presence of microbial pathogens in meat products. This laboratory is ISO 17025:2005-accredited by the NAT, under the Ministry of the National Economy, which is the national accrediting body in Hungary. This laboratory employs the validated methods of analysis that FSIS found to be equivalent.

The FSIS auditors reviewed the training records and certifications associated with the qualifications of the analysts, which demonstrated that they possess the academic qualifications, technical credentials, and accreditations required to conduct the analyses within their scope of accreditation. The documents reviewed also demonstrated that analysts had successfully participated in intra and inter-laboratory evaluations administered by the laboratory managers and accrediting bodies. The FSIS auditors reviewed reports of internal audits conducted by the NFCSO. Non-conformities reported by quality assurance personnel were communicated to laboratory managers, and corrective actions were implemented as short-term or long-term, depending on the nature of the non-conformities.

The FSIS auditors noted that some laboratory practices within its quality management system that might compromise the integrity of analyses or the CCA's capacity to prevent the shipment of potentially adulterated product to the United States.

- The laboratory was not documenting parameters associated with its testing methods for *Lm* (MLG 8.10) and *Salmonella* (ISO 6579:1998). Examples included:
  - No documentation of times (e.g., time in, time out) associated with incubation steps (both MLG 8.10 and ISO 6579:1998).
  - No documentation of the addition of iodine to the tetrathionate broth on the day of analysis (ISO 6579:1998).
  - The laboratory was using a timer to measure recorded sterilization times during media preparation that was not subject to calibration.

The FSIS auditors also noted the following deficiencies related specifically to the laboratory's implementation of the *MLG 8.10* testing method for *Lm*:

- The laboratory modified step 8.3.b. by adding an organism (*Staphylococcus aureus*) to the broth used as the negative control, whereas the actual method called for the use of pure University of Vermont medium (UVM) broth.
- Regarding the preparation of media used within step 8.6.2. (biochemical testing):
  - The preparation procedure for the xylose and rhamnose-based media was not followed according to manufacturer's instructions.
  - The container of xylose used in this preparation was expired.

FSIS's assessment of the significance of these findings considered the fact that the CCA provided sufficient evidence to demonstrate that the laboratory made immediate necessary changes to address these deficiencies prior to the FSIS auditors leaving the country. This included revising the records to include critical parameters; purchasing a calibrated timer; and ceasing to add any additional organisms to the UVM broth, thereby adhering to step 8.3.b. of the *MLG 8.10* as written. As to the accuracy of previous test results, the media used during the

biochemical testing phases of *MLG 8.10* is used only in latter confirmatory portions of the testing method. The FSIS auditors reviewed the laboratory records and verified that this point was not reached in recent testing history. Consequently, no expired or improperly prepared media was used in conjunction with product exported to the United States. Nevertheless, the findings indicate a need for the CCA to improve its oversight to ensure adherence to the prescribed methods as written, in addition to basic ISO 17025:2005 requirements.

There have not been any POE violations related to this component since the last FSIS audit in 2015. While the CCA maintains many of the technical elements to operate its inspection system, the failure to implement on-going verification sampling of FCS and environmental surfaces for *Lm* in establishments producing RTE PLE pork products does not meet FSIS's requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 15, 2017, in Budapest, Hungary, with NFCSO. At this meeting, the FSIS auditors identified the following significant audit findings. As a result of these audit findings, FSIS immediately began to increase POE sampling of pork product exported to the United States. The increased POE sampling will continue until the concerns related to these findings are resolved. In addition, FSIS requested that the CCA take immediate corrective actions to address these findings.

Government Oversight (e.g., Organization and Administration)

- Inspection personnel did not consistently document noncompliances identified during regular onsite verification activities and issued only verbal instructions to correct any identified deficiencies.
- The CCA has not provided adequate training to inspection personnel regarding basic HACCP system requirements; control of *Lm* in the post-lethality environment, and lethality in RTE fermented and dried products.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The CCA did not ensure that establishments maintained adequate hazard analyses, as evidenced by establishments' failures to identify all hazards, to include prerequisite programs, and to reference the supporting records.
- The CCA did not ensure that establishments maintained adequate HACCP plans, as evidenced by establishments' failures to identify specific frequencies of verification activities, to describe all aspects of corrective actions, and to maintain supporting evidence for the selection of critical control points.

Government Chemical Residue Testing Programs

- The online reporting system for entering laboratory samples does not detect omissions such as missing animal identification numbers on residue sample forms.

Government Microbiological Testing Programs

- The CCA's current RTE verification sampling program does not include on-going verification sampling of FCS and environmental surfaces (non-food contact) for *Lm*.
- The CCA did not document parameters associated with the testing methods for *Lm* and *Salmonella,* and did not implement the *Lm* testing method as prescribed.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
MCS Vagohid Zrt. 7622 Pecs Tuskesreti ut, hrsz. 40753	12/08/2017	HU 553 EK	Hungary
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/08/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fornetti Fagyasztott Pekaru Termelo es Kereskedelmi Kft. 6100 Kiskunfelegyhaza, Gateri u. 087/30 hrsz.	12/05/2017	HU 365 EK	Hungary
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Hungary's inspection officials during the establishment review:

14/51. The establishment's hazard analysis did not address chemical hazards (allergens, such as egg powder used in the final product) at the process steps for dry storage and mixing.

19/51. The establishment’s HACCP plan did not list the specific verification frequencies for direct observation of monitoring and records review.

19/51. The establishment’s schedule for calibration of process monitoring instruments was not included in the HACCP plan, however the process monitoring instruments were being calibrated on a regular basis.

20/51. The establishment’s HACCP plan did not address all parts of corrective actions for CCPs, specifically measures to prevent recurrence and identification of the cause of the deviation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/05/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pick Szeged Zrt. Alsomocsoladi Gyaregysege 7345 Alsomocsolad Alsomocsolad ut 2	12/07/2017	HU 86 EK	Hungary
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Hungary's inspection officials during the establishment review:

10/51. The surface of pallets where containers used for ready-to-eat (RTE), post-lethality-exposed product were stacked had not been adequately protected from cross-contamination. No product adulteration was observed.

14/51. The establishment did not consider a chemical (potassium sorbate) that was introduced at a process step (soaking of casings) in the hazard analysis.

14/51. The establishment did not consider product coming into direct contact with a food contact surface that is contaminated with *Listeria monocytogenes* (*Lm*) to be adulterated within the context of their *Lm* sampling program. However, there have been no positives identified in their sampling results for product contact surfaces in recent history.

14/51. The establishment did not include a primary product contact surface (plastic fingers of the packaging machine) in its *Lm* sampling program.

21/22/51. The hazard analysis for RTE products did not identify *Lm* in the post-lethality environment.

In addition, FSIS identified the following findings related to the implementation of Hungary's inspection system:

51. Official inspection personnel did not routinely conduct verification sampling of food contact and non-food contact surfaces for Lm in this establishment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/07/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dunakeszi Hutohaz Kft. . 2120 Dunakeszi Tozegtavi ut 11-13	12/11/2017	HU 55 EK	Hungary
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	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 .	O	41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	X
21. Reassessed adequacy of the HACCP plan.	O	**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

The following non-compliances were not identified by Hungary's inspection officials during the establishment review:

41/51. The ceilings above three freezer entryways presented a build-up of flaking frost which could contaminate employee clothing or the surface of pallets of product (wrapped in plastic) transiting this area. No direct product contamination identified.

48/51. Edible product was identified in the veterinary retention freezer. This area was designated only for product under official control.

In addition, FSIS identified the following findings related to the implementation of Hungary's inspection system:

51. Inspection personnel were not in the practice of documenting non-compliances identified during regular on-site visits, issuing only verbal instruction to correct any identified deficiencies. Routine documentation of non-compliances occurred only in conjunction with annual reviews led by members of the district office.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/11/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pick Szeged Zrt. Kozponti Gyara 6725 Szeged Szabadkai ut 18	12/06/2017	HU 7 EK	Hungary
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Hungary's inspection officials during the establishment review:

14/51. The establishment did not consider product coming into direct contact with a food contact surface that is contaminated with *Listeria monocytogenes* (*Lm*) to be adulterated within the context of their *Lm* sampling program. However, there have been no positives identified in their sampling results for product contact surfaces in recent history.

14/51. The establishment did not include a primary product contact surface (packaging machine) in its Lm sampling program.

19/51. The establishment's HACCP plan did not list the specific verification frequencies for direct observation of monitoring and records review.

19/51. The establishment's schedule for calibration of process monitoring instruments was not included in the HACCP plan, however the process monitoring instruments were being calibrated on a regular basis.

20/51. The establishment's HACCP plan did not address all parts of corrective actions for CCPs, specifically measures to prevent recurrence and identification of the cause of the deviation.

21/22/51. The hazard analysis of ready-to-eat (RTE) products did not identify *Lm* in the post-lethality environment.

38/51. Cobwebs, dust, and peeling tape were observed in the post-lethality environment where RTE product was stored and transited.

In addition, FSIS identified the following findings related to the implementation of Hungary's inspection system:

51. Official inspection personnel did not routinely conduct verification sampling of food contact and non-food contact surfaces for *Lm* in this establishment.

51. Official inspection personnel did not correctly identify the product category on export certificates under the HACCP process category "Not Heat – Treated Shelf Stable" product. While the actual product being exported to the United States is an RTE dried meat product, the product was being incorrectly certified under the acidified/fermented meat process category. The correct identification of the product category is an essential step in ensuring that inspection personnel verify that establishments control hazards associated with specific products within the context of their HACCP system.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/06/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Papai Hus Kft. f.a. 8500 Papa Kisfaludy u. 2.	11/30/2017	HU 6 EK	Hungary
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	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

The following non-compliances were not identified by Hungary's inspection officials during the establishment review:

10/51. Fat and meat particles were observed during pre-operational inspection in a sanitizer in the evisceration area, on a beam above the roast cutter, and inside the marination machine.

14/51. The establishment's hazard analysis did not address chemical hazards at the scalding step, where a defoaming agent was introduced.

15/51. The establishment did not separate two process steps (cooking and cooling) within the flow chart and hazard analysis. The establishment maintained one CCP for both cooking and cooling, which contained critical limits for two unrelated food safety hazards (i.e., destruction of microbial pathogens during cooking and germination of spore-forming bacteria during cooling).

16/51. The establishment did not maintain supporting documentation associated with the selection of the critical limits of the chilling CCP, however the critical limits for chilling were meeting FSIS regulatory guidance under Appendix B, Compliance Guidelines for Cooling Heat-Treat Meat and Poultry Products (Stabilization).

19/51. The establishment’s HACCP plan did not list the specific frequencies for direct observation of monitoring and records review.

19/51. The establishment’s schedule for calibration of process monitoring instruments was not included in the HACCP plan, however the process monitoring instruments were being calibrated on a regular basis.

20/51. The establishment’s HACCP plan did not address all parts of corrective actions under the zero tolerance CCP, specifically measures to prevent recurrence and identification of the cause of the deviation.

39/51. Rain was observed dripping from several portions a solarium style roof covering peripheral passage areas of the establishment. The FSIS auditors noted that these areas were used for the occasional storage of equipment (e.g., carcass gambrels) and carting of raw products between processing departments. While no product adulteration was observed, this issue had not been documented on daily inspection records nor during supervisory reviews. After the FSIS auditors identified this non-compliance, Hungary’s inspection officials committed to working with establishment management to develop immediate short-term measures to ensure the protection of product transiting these areas until the necessary roof repairs were accomplished. Short-term measures included the use of sealed carts and blocking-off of the affected passage areas.

51. Inspection personnel were not in the practice of documenting non-compliances identified during regular on-site visits, issuing only verbal instruction to correct any identified deficiencies.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/30/2017

Appendix B: Foreign Country Response to the Draft Final Audit Report

MINISTRY OF
AGRICULTURE

DR. LAJOS BOGNÁR
Chief Veterinary Officer
Deputy State Secretary for Food Chain Control

Ref: ÉlfF/14-4 /2018

Budapest 6th April 2018

For Mr. Todd Furey
Acting International Coordination Executive
Office of International Coordination

Food Safety and Inspection Service
United States Department of Agriculture

Washington D.C
1400 Independence Avenue, SW.
20250

E-mail: internationalcoordination@fsis.usda.gov

Subject: Response to FSIS letter dated on 7th March 2018 on the systemic findings related to the on-site audit in 2017

Dear Mr. Furey,

Following receipt of your letter dated on 7 March 2018 requesting further information and documentation on the corrective actions related to the systemic findings of the on-site audit conducted in Hungary in 2017, we have compiled a detailed set of answers and supporting documents which we send as an attachment to this letter.

We ask FSIS to evaluate our responses and we sincerely hope that the corrective measures and on-going verification policies developed and implemented by our services will be deemed sufficient and appropriate and with these corrective measures Hungary can maintain its current eligible status to export high quality food products to the U.S.

Should there be any issues related to the actions and documentation attached that need to be further clarified, please do not hesitate to contact us.

I am looking forward to our continued fruitful cooperation.

Yours sincerely,

FÖLDMŰVELÉSÜGYI MINISZTÉRIUM
ELVÉTTES ÁLLAMTITKÁR
* 1. *

Lajos Bognár DVM

H-1055 Budapest, Kossuth Lajos tér 11., Phone: (+36 1) 795-3785, Fax: (+36 1) 795-0564

Attachment: Hungary's responses to FSIS's letter dated on 7th March 2018 on the systemic findings related to the on-site audit in 2017

COMPONENT ONE: GOVERNMENT OVERSIGHT

- **Audit Finding:** The Central Competent Authority (CCA) has not provided adequate training to inspection personnel regarding basic Hazard Analysis and Critical Control Point (HACCP) system requirements; control of *Listeria monocytogenes* (*Lm*) in the post-lethality environment; and lethality in ready to eat (RTE) fermented and dried products.

  Further Information Needed: NFCSO needs to provide the revised training material. In addition, NFCSO needs to provide documentation demonstrating how and at what frequency inspection personnel will be evaluated on their knowledge of the revised material and United States (U.S.) requirements (e.g., supervisory reviews). Please include documentation describing how inspection personnel will be kept up-to-date on current FSIS requirements and policies.

NFCSO has updated and revised their training material based on all available information they gathered. From 1 April 2018 a training procedure is also in force which describes the requirements for all local official personnel supervising FSIS-approved establishments. There is also a set deadline of 30 September 2018 for all current inspectors to be trained again. The evaluation of the knowledge of inspectors is also included. Please find attached the compiled training material and a translation of the training procedure. MoA and NFCSO both appointed experts in their relevant units who subscribed to FSIS' newsletter service, and has to check regularly if any updates are available regarding the topics of the training material. Any new information obtained will be incorporated into the training material.

- **Audit Finding:** Inspection personnel did not consistently document non-compliances identified during regular on-site verification activities and issued only verbal instruction to correct any identified deficiencies.

  Further Information Needed: NFCSO needs to provide documentation describing how and at what frequency it will verify the implementation of this proposed corrective action. In addition, please provide updated inspection procedures requiring that inspection personnel document, in writing, any identified instances of noncompliance.

Please find attached the letter 02.4/106-2/2018. of 4 January 2018 by the NFCSO. It includes the order for local inspectors to document all non-compliances detected, and any corrective measures ordered. NFCSO also modified its checklist for use during the supervisory inspections every six months. The checklist now includes detailed inspection points regarding this matter. Please find attached the specimen checklist. NFCSO will pay special attention in their upcoming visits to the proper documentation of non-compliances.

COMPONENT FOUR: GOVERNMENT HACCP SYSTEM

- **Audit Finding:** The CCA did not identify multiple issues related to the hazard analysis, including failure to identify hazards and failure to list prerequisite programs and supporting documentation. The CCA did not identify multiple issues related to the contents of the HACCP plan including failure to list specific frequencies of verification activities, failure to list all parts of corrective actions, and failure to maintain support for the selection of critical control points.

  Further Information Needed: NFCSO needs to submit documentation (e.g., training materials, inspection procedures and frequencies, and supervisory reviews) identifying how and at what frequency it will verify that establishments 1) conduct a hazard analysis to identify any and all food safety hazards that can occur before, during, and after entry into the establishment; and 2) maintain supporting documentation for all decisions made in the hazard analysis (including support for decisions of "not reasonably likely to occur" due to the implementation of a prerequisite program).

  Furthermore, please include documentation demonstrating whether NFCSO requires and verifies that certified establishments validate their HACCP systems to ensure that they are designed and executed properly. Include documentation demonstrating whether NFCSO verifies that establishments maintain both components of HACCP validation: 1) scientific or technical support for the product that is produced, and 2) in-plant implementation data supporting that critical parameters are met during operation. Please also provide a description of how NFCSO verifies that the scientific or technical support being used as a validation document is appropriate for the product being produced (e.g., fermented and dried RTE pork products).

  Lastly, NFCSO needs to submit documentation (e.g., training materials, inspection procedures and frequencies, and supervisory reviews) identifying how and at what frequency it will verify that establishment HACCP plans identify critical control points and critical limits; list monitoring procedures and frequencies; list corrective actions; and list verification procedures and frequencies.

Hungarian establishments approved for producing food of animal origin are obliged to comply with HACCP rules laid down in Regulations EC 852/2004 and 853/2004. Official inspections are performed to evaluate the compliance with EU regulations. As a part of this process, in the case of new establishments or when an existing establishment introduces new activities that are subject to approval, the regional competent authorities perform inspections according to the "HACCP Guidance" (attachment) and make decisions based on the templates included in the referred guidance document, which the inspectors fill out during inspections. Beginning with 2018, inspectors of local competent authorities perform their inspection tasks on an activity-based approach (including HACCP based procedures, as described in the attached table) rather than the establishment-based approach applied in the past. Inspections are being performed at a minimum frequency of one inspection per year per approved activities, which means a more frequent inspection in export approved establishments since these establishments are typically approved for more than one activity.

Periodic inspections performed in U.S. approved establishments by the County Government Office and the NFCSO also contain questions on HACCP. Relevant checklists have been presented during the on-site audit and we also send the updated central level checklist as an attachment to this letter.

The establishments in question are also regularly audited by third party auditing bodies on HACCP and the results are presented by the establishments during official inspections (examples attached).

Based on the abovementioned it can be stated that the Hungarian competent authorities are maintaining and operating an inspection system that fully covers the inspection of HACCP based procedures as they are set in the EU law and thus maintaining a government oversight which is equivalent with the U.S. requirements. Hungarian competent authorities does not require and inspect against any additional requirements to these in terms of HACCP (i.e. 9 CFR 417), this was falsely stated and/or requested in previous communication (i.e. SRT).

- **Audit Finding:** The CCA did not identify deficiencies in establishment *Lm* sampling programs, including the failure to identify key food contact surfaces (FCS), and the failure to consider product coming into direct contact with a FCS that is contaminated with *Lm* to be adulterated.

  Further Information Needed: NFCSO needs to provide documentation describing how and at what frequency it will verify that establishment sampling plans identify and include food contact surfaces in the post-lethality environment.

  Furthermore, the January 4, 2018, letter sent to Dr. Pleva, NFCSO stated that establishments must comply with the "hold and test" program. Please provide documentation that describes how and at what frequency NFCSO verifies that establishments hold or retain control of product pending negative or non-violative government testing results. In addition, please provide documentation that describes how and at what frequency inspection personnel are verifying that certified establishments receive and confirm acceptable test results, from all samples of products tested for adulterants as defined by FSIS and designated for export to the U.S., prior to signing the pre-shipment review record.

  Lastly, NFCSO needs to submit official documentation (i.e., laws or regulations) demonstrating that Hungary considers product that has come into direct contact with FCS that has tested positive for *Lm*, through either an official government sample or establishment sample, to be adulterated and ineligible for export to the U.S. In addition, please provide the procedures and frequency used by inspection personnel to verify that product that has passed over a FCS that has tested positive for *Lm* is considered adulterated and not exported to the U.S.

NFCSO ordered all relevant establishments and local competent authorities to update their sampling plans regarding Lm sampling programs (letters 02.4/106-2/2018. and 02.4/106-3/2018.). All participants sent their updated programs on time. The first results of testing are

also available. As described in our previous letter, NFCSO will analyze the system after a 6 month initial period, and will amend the official program accordingly.

NFCSO issued further rules to all local competent authorities (letter 02.4/106-22/2018.) and to all US approved establishments (letter 02.4/106-23/2018.). The pre-shipment review document has to include the negative test results related to the updated Lm sampling programs. Local inspectors can not issue any health certificates without the mentioned negative results. This procedure guarantees that any product that has come into direct contact with FCS that has tested positive for Lm, through either an official government sample or establishment sample, is considered to be adulterated and ineligible for export to the U.S.

NFCSO also modified its checklist for use during the supervisory inspections every six months. The checklist now includes detailed inspection points regarding this matter. Please find attached the specimen checklist. NFCSO will pay special attention in their upcoming visits to the above mentioned requirements.

COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The online reporting system for entering laboratory samples and results is not designed to identify errors such as a missing animal identification number that was not included on a residue sample form submitted.

  NOTE: Although not listed in the December 18, 2017 letter sent to NFSCO, this was a systemic finding identified during FSIS's on-site audit. Therefore, we have provided a description of the further information needed to assess your corrective actions to this audit finding.

  Further Information Needed: NFCSO needs to provide documentation describing how it will address the design flaw in its online reporting system for entering laboratory samples and results. Please include corrective actions implemented to ensure the traceability of sampled product.

Annex 5 of FVM Decree No.10/2002. (I.23.) contains the rules of official sampling and sample handling which also stipulates that the laboratory must notify the County Government Office who took the sample on any offence on the rules for sampling, handling and sending the samples.

If the identification data for the animal is incomplete and can't be corrected, the sample will be rejected.
If the deficiencies can be corrected, the sample reception office will contact the official veterinarian to provide the missing data. The corrected sampling document shall be sent electronically.
The IT system will be updated so that the data of the sample cannot be recorded without the ID of the animal (i.e. the ENAR number is missing, incorrect. or incomplete).

Official guidelines for the competent authority are also in place describing the sampling procedure in general and the specific procedures for the residue sampling as well, which the competent authority must comply with. (attachment)

COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- **Audit Finding:** The CCA's RTE verification sampling program does not include on-going verification sampling of food contact surfaces (FCS) and environmental surfaces (non-food contact) for *Lm*.

  Further Information Needed: NFCSO needs to submit an updated microbiological sampling plan that clearly describes how and at what frequency it will conduct ongoing government verification sampling and testing for *Lm* on FCS and environmental or non-FCS surfaces.

  In addition, please provide documentation identifying whether NFCSO requires establishments **to perform corrective actions when either an establishment sample or government sample is identified as positive**, and how and at what frequency inspection personnel verify the adequacy of the corrective actions. Further, please provide documentation describing how and at what frequency inspection personnel review and verify establishment sampling and testing procedures and results. Lastly, include whether NFCSO performs follow-up sampling in response to positive test results, and any additional enforcement strategies NFCSO takes in response to positive results.

NFCSO ordered all relevant establishments and local competent authorities to update their sampling plans regarding Lm sampling programs (letters 02.4/106-2/2018. and 02.4/106-3/2018.). All participants sent their updated programs on time. The first results of testing are also available. As described in our previous letter, NFCSO will analyze the system after a 6 month initial period, and will amend the official program accordingly.

NFCSO issued further rules to all local competent authorities (letter 02.4/106-22/2018.) and to all US approved establishments (letter 02.4/106-23/2018.). The pre-shipment review document has to include the negative test results related to the updated Lm sampling programs. Local inspectors can not issue any health certificates without the mentioned negative results. This procedure guarantees that any product that has come into direct contact with FCS that has tested positive for Lm, through either an official government sample or establishment sample, is considered to be adulterated and ineligible for export to the U.S.

In case of a non-compliant result from FCS, the affected batch must be excluded from U.S. export and the competent authority is obliged to take additional measures while also increasing the official verification sampling frequency as well, as stipulated in letters 02.4/106-2/2018. and 02.4/106/22/2018.

The above described sampling program has been incorporated (as part of the "1.26. Special Control Plans") to the National Food Chain Control Plan. The last yearly version was issued by letter ÉFÁT/121/2018. being in force from 1 April 2018.

Parallel to the government verification sampling, the establishments have also updated their microbiological sampling plans according to the orders of NFCSO's letter 02.4/106-3/2018 sent on the 5th of January 2018. The updated sampling plans of the establishments were approved by the local competent authority.

- **Audit Finding:** The CCA did not document critical parameters associated with the government testing methods for *Lm* and *Salmonella,* and did not implement the *Lm* testing method as prescribed.

  Further Information Needed: NFCSO needs to provide documentation identifying whether any changes were made to the oversight of government laboratories to ensure that testing methods and critical parameters are being followed and met.

NFCSO, System Management and Supervision Directorate, Supervision Unit regularly supervises the activity of the different professional directorates in the frame of independent audits. If national, international or foreign institutions supervising the activity of any organizational unit of NFCSO identify non-compliances, Supervision Unit has the task to check if appropriate actions were taken, and monitoring the implementation of corrective measures.

Supervision Unit will perform on-site check in the laboratory to ensure that the testing methods of Salmonella and Lm are completely in line with the requirements. These checks will be ad hoc and planned. The first planned audit will be organized in September 2018.

As USDA-FDIS audit identified non-compliances in the application and the detailed documentation of Salmonella and Lm methods, on the next internal audit to be performed in the frame of the accreditation of Food Microbiological National Reference Laboratory at 23 April 2018 a special attention will be paid to this area.