FINAL REPORT OF AN AUDIT CONDUCTED IN

HUNGARY

JULY 22 THROUGH AUGUST 2, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

January 23, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 22 through August 2, 2019. The purpose of the audit was to determine whether Hungary's food safety inspection system governing meat (i.e., beef, veal, goat, lamb, mutton, and 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 currently exports raw intact; heat treated but not fully-cooked-not shelf stable; ready-to-eat (RTE) acidified/fermented (without cooking); RTE dried; and RTE fully-cooked 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The National Food Chain Safety Office (NFCSO) inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing and stamping of the export certificate.

GOVERNMENT STATUATORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The NFCSO does not require certified establishments to ensure zero tolerance requirements for carcasses to be free of fecal material, ingesta, and milk are met prior to entering the chill cooler.
- The NFCSO inspection personnel do not conduct offline verification of zero tolerance requirements to ensure carcasses are free of fecal material, ingesta, and milk prior to entering the chill cooler.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- At three of the five audited establishments, the hazard analysis identified the biological hazard of *Salmonella* as likely to occur with no associated critical control point (CCP) to control the identified hazard.
- At three of the five audited establishments, the written HACCP plan did not meet NFCSO requirements to include written procedures or frequencies for all required verification procedures.
- At one audited establishment, the written HACCP plan did not meet NFCSO requirements to include all required parts of corrective actions for a zero tolerance fecal material, milk, and ingesta CCP, a repeat finding of the last FSIS audit.

During the audit exit meeting on August 2, 2019, the NFCSO committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of NFCSO's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY 1

III. BACKGROUND 4

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION) 5

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) 8

VI. COMPONENT THREE: GOVERNMENT SANITATION 10

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM 11

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS 12

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS 13

X. CONCLUSIONS AND NEXT STEPS 14

APPENDICES 16

Appendix A: Individual Foreign Establishment Audit Checklists

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

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Hungary's food safety system July 22 - August 2, 2019. The audit began with an entrance meeting on July 22, 2019, 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). During the audit exit meeting on August 2, 2019, the NFCSO committed to address the preliminary findings. Representatives from NFCSO accompanied the FSIS auditors throughout the entire audit.

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 meat (i.e., beef, veal, goat, lamb, mutton, and 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 currently exports raw intact; heat treated but not fully-cooked-not shelf stable; ready-to-eat (RTE) acidified/fermented (without cooking); RTE dried; and RTE fully-cooked pork products to the United States. Hungary is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Ground product; other non-intact; and sausage.
Raw - Intact	Raw intact pork	Boneless manufacturing trimmings; carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals.
Not Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking)	Other - not sliced; other - sliced; sausage/salami - not sliced; and sausage/salami - sliced.
Not Heat Treated - Shelf Stable	RTE dried meat	Ham - not sliced; ham - sliced; jerky; other - not sliced; and other - sliced.
Heat Treated - Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/potpies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes the following species: beef, veal, goat, lamb, mutton, and pork.

Fully Cooked - Not Shelf Stable	RTE fully-cooked meat	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Fully Cooked - Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats; oils; sandwiches/filled rolls/wraps; sauces; sausage products; smoked parts; and soups.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Hungary as subject to the following restrictions. Beef imported from Hungary is subject to the foot-and-mouth disease (FMD) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.11, and bovine spongiform encephalopathy (BSE) requirements specified in 9 CFR 94.18 and/or 9 CFR 94.19. Pork imported from Hungary is subject to the African swine fever (ASF) requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR §4.31, swine vesicular disease requirements specified in 9 CFR 94.13, and FMD requirements specified in 9 CFR 94.11.

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) reinspection and 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).

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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at the NFCSO headquarters, one county government office, and five local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors visited a sample of five establishments which were selected from a total of six establishments certified to export to the United States. This included three pork slaughter and processing establishments and two pork processing establishments.

During each establishment visit, the FSIS auditors specifically evaluated the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed NFCSO's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

Additionally, two government operated laboratories, one conducting microbiological analyses and the other conducting chemical residue analyses, were audited to verify their abilities to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• NFCSO, Budapest
	County	1	• Baranya County Government Office (CGO), Baranya
Laboratories		2	• NFCSO National Reference Laboratory for Microbiology, Budapest
			• NFCSO National Reference Laboratory for Residues, Budapest
Pork slaughter and processing establishments		3	• Establishment No. HU 6 EK, Pápai Hús Kft., Pápa
			• Establishment No. HU 23 EK, Hungary Meat Kft., Kiskunfélegyháza
			• Establishment No. HU 1360 EK, MCs Vágóhíd Zrt., Mohács
Pork processing establishments		2	• Establishment No. HU 7 EK, Pick Szeged Zrt., Központi Gyára, Szeged
			• Establishment No. HU 86 EK, Pick Szeged Zrt., Alsómocsoládi Gyáregysége, Alsómocsoládi

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Hungary's inspection system for meat (i.e., beef, veal, goat, lamb, mutton, and pork) products 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 *Agreement on the Application of Sanitary and Phytosanitary Measures*; and includes the following:

- Regulation European Commission (EC) No. 999/2001;
- Regulation (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. 589/2008;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 37/2010;
- Regulation (EC) No. 16/2011;
- Regulation (EU) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From March 1, 2016 through February 28, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,879,088 pounds of pork products exported by Hungary to the United States. These products imported into the United States included 2,529 pounds of raw intact pork, 888,177 pounds of NRTE otherwise processed pork, 43,753 pounds of RTE dried pork, 457,972 pounds of RTE fully cooked pork, and 486,657 pounds of RTE acidified/fermented pork (without cooking).

Of these amounts, additional types of inspection were performed on a total of 463,662 pounds of pork products consisting of 80,045 pounds of NRTE otherwise processed pork, 14,201 pounds of RTE dried pork, 204,532 pounds of RTE fully cooked pork, and 164,884 pounds of RTE acidified/fermented pork (without cooking), including testing for chemical residues and microbiological pathogens *Salmonella* and *Listeria monocytogenes* (*Lm)* in pork products for which no products were rejected for issues related to public health.

The previous audit in November through December of 2017 identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- Inspection personnel did not consistently document noncompliances identified during regular on-site 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 POINT (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 (CCPs).

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.

The FSIS auditors reviewed and analyzed Hungary's SRT responses and supporting documentation. During the on-site audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Hungary's food safety inspection system governing meat (beef, veal, goat, lamb, mutton, and pork) products is being implemented as documented in the country's SRT responses and supporting documentation. The FSIS auditors verified that the corrective actions for the previously reported findings were implemented and effective in resolving the findings except as noted within the following audit report.

The FSIS final audit reports for Hungary's food safety inspection system are available on the FSIS website at: https://www.fsis.usda.gov/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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 technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The NFCSO is the CCA responsible for animal health and welfare, food and feed safety, and international affairs. The NFCSO operates under the direction and supervision of the Ministry of Agriculture (MoA). The MoA, through NFCSO, directs the County Government Offices (CGOs) and District Government Offices (DGOs) to develop and implement plans, procedures, and guidelines for meat inspection.

The NFCSO provides overall regulatory oversight of establishments certified to export products to the United States, with the CGOs as the second level of inspection and the DGOs responsible for direct oversight of daily activities within certified establishments. The FSIS auditors verified that no changes in the staffing of governmental personnel directed by NFCSO has occurred since the last audit in 2017.

The CGOs and DGOs work in conjunction to assign official employees to eligible establishments to ensure adequate staffing for all duties for production of products to be exported to the United States. A duty roster is maintained with extra personnel who are available to ensure FSIS inspection requirements of ante-mortem, humane handling, post-mortem, processing, and export certification are performed by Official Veterinarians (OV) and official auxiliary inspection personnel. The FSIS auditors verified through record review and observations that staffing programs were sufficient to ensure an effective level of oversight was maintained as described in the SRT.

The FSIS auditors verified through records review and observations that DGO in-plant inspection personnel conduct inspection activities at least once per shift for processing establishments. The DGO in-plant inspection personnel are responsible for conducting verification procedures and performing post-mortem inspection of each head, carcass, and viscera during slaughter operations in establishments that are certified to produce products for export to the United States.

The FSIS auditors verified through records review and interviews that NFCSO receives and reacts accordingly to results of laboratory testing and has procedures in place to notify FSIS of the shipment of adulterated products. The NFCSO has the ability to take enforcement actions if a certified establishment does not meet the requirements of NFCSO.

The DGO OV ensures the inspection and certification of product for export in accordance with FSIS requirements. The OV inspects product integrity of packages, labeling of packages, temperature of product, and quantity to be certified. During the export certification process, the OV is able to verify product was produced for United States export and is eligible based on the product information provided by the establishment (i.e., daily production records). The OV certifies the shipment by use of an official stamp unique to that OV and his signature on a bilingual health certificate. The FSIS auditors verified through records review and observations that controls are in place to prevent misuse or fraudulent activities during the export certification process.

Certification of product for export does not occur until microbiological test results of the establishment or official NFCSO microbiological testing results are received as acceptable. If an OV suspects or chooses to sample an animal for any chemical residues under the targeted testing program based on observations during ante-mortem or post-mortem inspections, that carcass is held pending acceptable test results. For testing conducted under the routine residue monitoring program however, the following was identified.

- The NFCSO inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing and stamping of the export certificate.

The FSIS auditors verified through records review and interviews that the CGO and DGO employees have met pre-employment requirements of NFCSO including a veterinary degree for OVs, and specialized experience for official auxiliary personnel. The NFCSO also indicated in interviews that training sessions were held in September of 2018 and included specialized training pertaining to United States requirements including animal welfare, ante-mortem inspection, post-mortem inspection, sanitation standard operating procedures (sanitation SOPs), HACCP, hygiene and sanitation performance standards, RTE *Lm* requirements, sample collection procedures for microbiological testing at slaughter and microbiological testing at processing, and the export certification process. The NFCSO also indicated that any changes in FSIS requirements are made available through an intranet document and are also communicated directly through email, by way of training events, and through mailing of a hard copy document to official inspection offices and establishments.

The NFCSO has the legal authority and responsibility to certify and de-certify establishments as eligible to export product to the United States. An establishment is certified as eligible through a clearly defined process. This process includes the following, the establishment applies for certification to the CGO, and the CGO forwards the application to NFCSO with the establishment's most recent CGO quarterly inspection result. The NFCSO reviews the application and will then carry out an on-site inspection of the establishment with the CGO. The NFCSO identifies any deficiencies and requires the establishment to submit an action plan and correct deficiencies after which NFCSO or the CGO performs an additional on-site inspection. If the deficiencies are corrected, NFCSO submits the facility for certification to the MoA, who then notifies FSIS that the facility has been certified as eligible to export product to the United States.

The FSIS auditors verified through records review and interviews that the following supervisory reviews occur: NFCSO personnel perform reviews twice annually, CGO personnel perform quarterly reviews, and the DGO OV of the establishment performs monthly reviews. Reviews performed by NFCSO, CGO, and DGO officials include evaluation of establishment actions in response to the previous supervisory review, on-site survey or audit of the establishment during operations, and the DGO documentation of inspection activities, review of facility conditions, sanitation SOPs, and HACCP programs and records, establishment and inspection testing programs and records, and traceability records of products. Additionally, the DGO veterinary officer performs twice yearly performance reviews of the in-plant OV who is responsible for oversight of all activities within a certified establishment.

The NFCSO provides direct oversight of government-operated laboratories which are responsible for analysis of all official residue and microbiological samples. The NFCSO requires the International Organization for Standardization (ISO) standard 17025, *General requirements for the competence of testing and calibration laboratories*, accreditation through independent audits and a yearly accreditation audit by the National Accreditation Authority (NAA) which includes a review of mandatory competency testing completed by each laboratory. The NFCSO verifies that laboratories continue to meet the minimum ISO standards through the evaluation of audit reports and copies of the accreditation. The FSIS auditors reviewed the most recent accreditation reports available at both visits to the National Residue Laboratory and National Microbiology Laboratory and confirmed that any identified findings were addressed in a timely manner.

The FSIS analysis and on-site verification activities indicated that NFCSO's food safety inspection systems have an organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. However, FSIS identified findings regarding the certification of products for export prior to all routine residue test results availability as noted above. The FSIS auditors confirmed that no affected product was exported to the United States based on a review of records.

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 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 each and every carcass and parts; controls over condemned materials; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified by review of supervisory records and interviews that supervisors from NFCSO, CGOs, and DGOs conduct supervisory reviews at the stated frequencies of twice annually, quarterly, and monthly, respectively. In addition, the FSIS auditors verified that the supervisors possessed the knowledge of EC requirements necessary for conducting supervisory reviews and establishment audits. The FSIS auditors verified that certified establishments responded to findings with an action plan that was submitted and verified as completed by official inspection personnel on-site and during the next supervisory review.

For movement of animals within Hungary, an animal health certificate signed and stamped by an OV is required in order for animals to be received at a slaughter establishment. Shipments of live animals are also accompanied by an attestation and record of animal health provided by the farm operator indicating any treatment of animals and the required withdrawal periods associated with all such treatments. The signed and stamped health certificate allows the in plant OV to confirm all requirements for animal health and the origin of the animals which affects disease statuses outlined by APHIS. In addition, the FSIS auditors verified that establishments have a

recall plan in place and can trace products forward in the event of a recall, as required by NFCSO.

The NFCSO veterinarian performs ante-mortem inspection on every shipment of swine animals prior to slaughter at a certified establishment. The FSIS auditors observed that the audited slaughter establishments provide designated areas for observation and further examination of suspect animals. Currently in Hungary, ten percent of all incoming live swine are temperature checked prior to harvest as a surveillance activity for ASF. Additionally, any swine that arrive dead are condemned as ineligible for human consumption and are subject to veterinary inspection and further testing for ASF as an additional surveillance activity. The FSIS auditors reviewed inspection records and observed execution of ante-mortem procedures that demonstrate inspection personnel perform ante-mortem inspection on all incoming swine animals.

The FSIS auditors also observed implementation of the humane handling programs at the audited slaughter establishments which are conducted in accordance with Regulation (EC) No. 1099/2009. The OV directly observes unloading of swine animals, the movement of animals to and within pens and to the harvest location, that animals have access to water or feed if held for 24 hours or more, the proper stunning of animals, and also verifies maintenance and conditions of the holding pens.

The FSIS auditors verified that government inspection personnel perform post-mortem inspection consistent with FSIS requirements at the time of slaughter. The FSIS auditors directly observed the implementation of NFCSO's inspection procedures during post-mortem inspection presentation, identification, examination, and disposition of carcasses and parts. The FSIS auditors verified that NFCSO requires official inspection personnel perform monitoring of each carcass for visible fecal material during the post-mortem carcass by carcass inspection process.

Official inspectors at post-mortem inspection stations were observed identifying carcasses for trimming, if contamination was observed. All carcasses railed out during post-mortem inspection must be re-inspected by an OV prior to being released back into the process. The FSIS auditors verified that OVs observe the actions of official auxiliary inspectors performing on-line post-mortem inspection procedures. The FSIS auditors identified the following:

- The NFCSO does not require certified establishments to ensure zero tolerance requirements for carcasses to be free of fecal material, ingesta, and milk are met prior to entering the chill cooler.
- The NFCSO inspection personnel do not conduct offline verification of zero tolerance requirements to ensure carcasses are free of fecal material, ingesta, and milk prior to entering the chill cooler.

The NFCSO requires certified establishments to segregate and store inedible products in a separate area from edible products. In addition, containers used for collecting inedible products must be conspicuously marked and easily distinguished from other containers. The FSIS auditors observed the handling and storage of condemned and inedible materials at the audited establishments and found no concerns.

FSIS concluded that Hungary's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component; however, systemic findings of concern regarding zero tolerance requirements and verification procedures were identified. As a result of the FSIS auditors' observations, NFCSO took immediate enforcement actions, including delistment of one establishment, in order to ensure that no product would be certified for export to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components 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 verified that NFCSO requires establishments certified for exporting product to the United States to develop and implement sanitation SOPs. The FSIS auditors confirmed that in-plant inspection personnel are required to conduct daily verification procedures of the implementation of each establishment's sanitation program. The FSIS auditors observed an isolated finding that NFCSO did not identify that one certified facility failed to adequately develop sanitation SOPs.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing in-plant inspection personnel conducting pre-operational sanitation verification inspection in one of the audited establishments. The OV's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The OV conducts pre-operational sanitation verification on a daily basis prior to production of product designated for export to the United States in accordance with NFCSO's established procedures.

The FSIS auditors observed the OV's verification of operational sanitation procedures in each audited certified establishment. The OVs are responsible for verification of sanitary operations during carcass dressing at slaughter facilities, and for verification of sanitary operations at RTE facilities. The FSIS auditors verified carcass dressing, and sanitation procedures through direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all audited establishments. The FSIS auditors observed an isolated finding that official in-plant inspection personnel did not perform or document verification of daily operational sanitation results in one certified establishment. NFCSO officials indicated that corrective actions would be taken to ensure performance and documentation of operational sanitation occurs on a daily basis.

FSIS concluded that Hungary's food safety system requires all establishments certified to export to the United States to develop, implement, and maintain sanitation SOPs to prevent the creation of insanitary conditions and contamination of products. However, the FSIS auditors identified isolated findings including one establishment did not adequately develop sanitation SOPs; and at one certified establishment official in-plant inspection personnel did not perform or document

verification of daily operational sanitation results. These isolated findings are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

The FSIS auditors noted that NFCSO requires establishments to develop and implement HACCP programs in accordance with Regulation (EC) Nos. 852/2004, 853/2004, and 882/2004. NFCSO maintains and outlines Hungarian requirements for HACCP in the *Official Guide 11th Edition.* The FSIS auditors verified that certified establishments' HACCP programs included written hazard analysis which identified hazards appropriate to the process occurring at each facility along with a flow chart. The FSIS auditors also verified that certified establishments exporting products to the United States perform a pre-shipment review prior to the release of product for shipment.

The OVs' verification of establishments' HACCP systems included activities such as the evaluation of the establishments' written HACCP programs, observing establishment personnel perform monitoring and verification procedures, corrective actions, and reviewing recordkeeping documents. The FSIS auditors observed and reviewed records of establishment CCP monitoring and ongoing verification procedures. The FSIS auditors identified the following:

- At three of the five audited establishments, the hazard analysis identified the biological hazard of *Salmonella* as likely to occur with no associated CCP to control the identified hazard.
- At three of the five audited establishments, the written HACCP plan did not meet NFCSO requirements to include written procedures or frequencies for all required verification procedures.
- At one establishment, the written HACCP plan did not meet NFCSO requirements to include all required parts of corrective actions for a zero tolerance fecal material, milk, and ingesta CCP, a repeat finding of the last FSIS audit.

The NFCSO has not effectively ensured that all certified establishments exporting product to the United States have developed and implemented adequate HACCP systems. The FSIS auditors also identified an isolated finding of a certified establishment failing to record the time of completion of verification activities, this finding is noted in the individual establishment checklist provided in Appendix A of this report. The NFCSO subsequently took immediate enforcement actions, including delistment of one establishment, in order to ensure that no product would be certified for export to the United States until corrective actions could be fully implemented by the establishment and verified by the CCA.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety 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.

Prior to the on-site visit, FSIS' residue experts reviewed Hungary's National Residue Program (NRP) testing results, associated methods of analysis, and SRT responses outlining the structure of Hungary's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The FSIS auditors verified through records review and direct observations that the NRP is organized and administered by NFCSO, which manages the national random sampling and testing program for chemical residues. Planning of the NRP is based on previous years' results as well as guidelines within EC Directive Nos. 96/22/EC and 96/23/EC. The FSIS auditors confirmed implementation of the NRP through review of records and observations at the NFCSO national reference laboratory for chemicals in Budapest, the CGO in Baranya, and during each site visit at certified establishments conducting slaughter operations. The FSIS auditors confirmed that the NRP sampling schedules included all eligible certified establishments.

The FSIS auditors verified that in-plant OVs collect routine residue samples and may choose to collect additional targeted residue samples based on dispositions and observations made during performance of ante-mortem and post-mortem inspections. All residue samples are transported to an NFCSO laboratory for analysis through official government paid workers who have routine routes to pick up samples directly from certified establishments, thereby maintaining official government control of all samples. Receipt of samples, tracking of samples, handling and analysis, and reporting of results were reviewed by the FSIS auditors at the chemical residue laboratory. The NFCSO national reference chemical residue laboratory is accredited by the NAA and maintains ISO 17025 accreditation. The FSIS auditors reviewed the previous audit reports and confirmed that the laboratory responded to correct any findings identified during the audit process.

The FSIS auditors confirmed that when a carcass is tested during routine NRP monitoring, there is no government requirement to hold the tested carcass pending receipt of acceptable test results. This observation is identified as a finding in Component One: Government Oversight. The FSIS auditors also confirmed that no affected product was exported to the United States based on a review of records. The NFCSO officials stated that the routine monitoring program considers the controls in place regarding receipt of all animals which include signed declarations of any treatments and associated withdrawal periods.

Results of laboratory analysis are reported to NFCSO, the CGO, the DGO, and the in-plant official who submitted the sample. The acceptability of test results is based on Regulation (EC) No. 37/2010 and FSIS-specific requirements which identifies banned substances with zero

tolerance levels and substances with maximum residue levels permitted in food stuffs. If a maximum residue level is exceeded or a prohibited substance is detected, the NFCSO initiates an investigation into the cause. In addition, the movement of livestock from the farm of origin is halted until the investigation can be satisfactorily completed. The FSIS auditors confirmed during the on-site visit to the NFCSO national reference chemical laboratory that if a residue violation occurs, the laboratory immediately notifies the NFCSO headquarters, the CGO, the DGO, and the in-plant official who submitted the sample to ensure all affected product is identified.

The FSIS analysis and on-site verification activities indicate that NFCSO continues to maintain the legal authority to regulate, plan, and perform surveillance that are aimed at prevention and control of the presence of residues of veterinary drugs and contaminants in products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

Prior to the on-site visit, FSIS microbiologists reviewed Hungary's national microbiological sampling and testing programs, laboratory methods of analysis, and SRT responses outlining the structure of NFCSO's microbiological verification sampling and testing programs. Since the last FSIS audit, NFCSO has implemented testing of food contact and environmental surfaces for *Lm* by OVs within each certified establishment in response to the FSIS 2017 audit findings.

The FSIS auditors verified that certified slaughter establishments producing product for export to the United States may choose what indicator organisms to sample for, either generic *Escherichia coli* (*E. coli*) or *Enterobacteriaceae.* The FSIS auditors observed that all certified slaughter facilities perform both generic *E. coli* and *Enterobacteriaceae* testing and analysis. The FSIS auditors verified through review of records that certified establishments adhere to written sampling frequencies for generic *E. coli* as described in 9 CFR 310.25 and for *Enterobacteriaceae* as described in Regulation (EC) No. 2073/2005. The FSIS auditors verified that establishments adhere to requirements and take actions when results exceed established criteria, or according to EC requirements for *Enterobacteriaceae*.

The NFCSO has developed *Salmonella* official sampling and testing programs for chilled carcasses which are implemented by official inspection personnel performing in-plant sampling and an NFCSO microbiological laboratory performing analysis of the samples. *Salmonella* testing is performed on a daily basis for 50 consecutive days, with a maximum allowable number of positive test results as six samples. If an establishment exceeds six positive samples, it is delisted as eligible for producing product for export to the United States until such time that corrective actions can be proffered, completed, and verified through subsequent follow-up *Salmonella* testing. If the results of testing do not exceed six positive *Salmonella* test results,

official inspection personnel will continue to sample at a reduced rate of once per week. The FSIS auditors did not identify any concerns regarding sample collection procedures or the NFCSO testing methods regarding the *Salmonella* sampling programs.

The FSIS auditors verified the NFCSO implementation of sampling for *Salmonella* and *Lm* in accordance with the document "*US Monitoring Surveys 2019*" which provides the NFCSO sampling plan for food contact surfaces, environmental surface swabs, and product samples specific to each certified establishment. All RTE products currently produced and certified for export to the United States are included in the NFCSO sampling plan. The FSIS auditors also verified that certified establishments instituted testing for *Lm* in order to ensure control and prevention of adulteration in the post-lethality environment.

The FSIS auditors visited the NFCSO national reference microbiological laboratory located in Budapest. The NAA conducts an annual technical review of this laboratory to maintain the ISO 17025 accreditation. The NFCSO microbiological laboratory is responsible for screening and confirmation analyses of official samples and uses testing methodologies for official analysis of *Salmonella* and *Lm* in accordance with ISO 6579:2006, *Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of Salmonella - Part 1 detection of Salmonella spp.*, and the FSIS Microbiology Laboratory Guidebook 8.10.2017, respectively. During the laboratory visit, the FSIS auditors reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, data capture, sample storage, equipment calibration, media preparation and storage, analytical controls, and reporting of results with no issues of concern identified.

The FSIS analysis and on-site verification activities indicate that NFCSO maintains the legal authority to implement its microbiological sampling and testing programs to ensure that products are safe and wholesome. There have not been any POE violations related to this component since the last FSIS audit. The FSIS auditors did identify isolated findings which are included in the individual establishment checklists provided in Appendix A of this report.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 2, 2019, in Budapest, Hungary, with NFCSO. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

- NFCSO inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing and stamping of the export certificate.

GOVERNMENT STATUATORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The NFCSO does not require certified establishments to ensure zero tolerance requirements for carcasses to be free of fecal material, ingesta, and milk are met prior to entering the chill cooler.
- The NFCSO inspection personnel do not conduct offline verification of zero tolerance requirements to ensure carcasses are free of fecal material, ingesta, and milk prior to entering the chill cooler.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- At three of the five audited establishments, the hazard analysis identified the biological hazard of *Salmonella* as likely to occur with no associated CCP to control the identified hazard.
- At three of the five audited establishments, the written HACCP plan did not meet NFCSO requirements to include written procedures or frequencies for all required verification procedures.
- At one audited establishment, the written HACCP plan did not meet NFCSO requirements to include all required parts of corrective actions for a zero tolerance fecal material, milk, and ingesta CCP, a repeat finding of the last FSIS audit.

During the audit exit meeting, NFCSO committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of NFCSO'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
Papai Hus Kft. f.a. . 8500 Papa Kisfaludy u. 2.	07/31/2019	6	Hungary
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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 .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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.	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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	X
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

15) The establishment does not identify procedures or frequency of the verification Direct Observation of monitoring. This is a repeat finding at this establishment.

20) The establishment's HACCP Plan does not include procedures to identify the cause or measures to prevent recurrence of the deviation of zero tolerance fecal. This is a repeat finding at this establishment.

39) Flaking paint in ham removal room with paint flakes on work areas.

41) Beaded condensation above products in coolers which had dripped on product carcasses.

45) Stainless product bins were cracked. Piping for cure solution could not be disassembled to allow for inspection/adequate cleaning. Rusted gambrels, rusted overhead structure (rails, brackets, etc.) in areas including slaughter floor, deboning area, curing area, ham area.

46) Rusted areas were over exposed product, rail dust/dirt was also observed on product and product contact surfaces. Product tubs stored near the floor and next to worker stands which could contact boots.

50) Government inspection personnel do not conduct or document verification of operational sanitation on a daily basis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/31/2019

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	07/26/2019	7	Hungary
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X
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.	
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.	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	X
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

60. Observation of the Establishment

10) Establishment does not conduct a complete clean-up (to include complete disassembly of equipment) prior to production of product for the United States.

14) The establishment's written HACCP Hazard Analysis identified microbiological hazards that were reasonably likely to occur however, they did not identify lethality controls (Salmonella) for dry curing RTE salami (Sausage) processing steps although the processes had a scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.

22) The FSIS auditors observed that the establishment does not include/record the time of the event for the completion of verification (record review, direct observation).

39) Overhead rails and equipment used in the salami stuffing area were observed to be rusted. Peeling paint and overhead dust-dirt observed outside of the smoke rooms.

45) In the deboning area; conveyor belt scrapers observed in deteriorating condition, residue observed in stainless product tubs, cubing/flaking machine observed to have heavy wear on metal parts with metal missing due to rubbing of parts. Equipment was not disassembled to the extent necessary to allow for adequate cleaning, or inspection by the government inspector.

46) Residues from previous operations were observed in the following areas due to lack of disassembly and complete clean-up; salami stuffing area, RTE product sorting area, and RTE product packaging area. Exposed product in cooler was observed to have multiple areas of rail dirt, grease contamination.

36) Establishment does not conduct a complete clean-up (to include complete disassembly of equipment) prior to production of product for the United States. Establishment Lm Control Program did not include a listing of all product contact sites; during the establishment tour FSIS auditors observed additional contact sites of employee aprons, and employee work coats.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/26/2019

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
Hungary Meat Kft. 6100 Kiskunfelegyhaza, Majsai ut 30.	07/25/2019	23	Hungary
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
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.	X
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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

7, 10) The establishment SSOP program does not include procedures to be conducted during operations to prevent contamination or adulteration of product. Additionally, the establishment's SSOP program does not include a frequency of monitoring of operational sanitation.

14) The establishment's Hazard Analysis identifies a biological hazard (microbiological--Salmonella) as likely to occur, with no associated Critical Control Point to control the identified hazard.

15) The establishment's written HACCP Plan does not include procedures or frequency of calibration of thermometers used for monitoring of CCP critical limit. The establishment's written HACCP Plan does not include procedures or frequency of the verification procedure of Direct Observation.

36) During the establishment tour, FSIS auditors observed that the competent authority had one inspection person stationed at the end of the viscera-head-carcass inspection area who served as the final rail inspector. No additional government verification of carcass dressing or zero tolerance occurs prior to carcasses entering the chill cooler. During the establishment tour, the FSIS auditors observed one carcass in the cooler with a large area of yellow staining from the evisceration process.

39) Overhead rails with heavy buildup of grease and dirt.

41) Areas of beaded condensation in coolers above carcasses.

46) Numerous carcasses within the cooler and entering into the deboning area were observed to be affected by rail dirt-grease. CCA indicated because of the known problem with rail dirt-grease, the establishment has instituted the use of a person assigned to identify affected carcasses. FSIS auditors observed that this designated establishment employee was unable to identify all affected carcasses. Additionally, affected carcasses were observed to routinely come in contact with non-affected carcasses thereby causing cross contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/25/2019

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 Alsomocsoladi UT 2	07/30/2019	86	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 .	
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	X
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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

36) Establishment Lm Control Program did not include all product contact sites in their list of sites to be tested; that come in contact with product; during the establishment tour FSIS auditors observed an additional contact site of employee aprons, and employee arm plastic wrap.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/30/2019

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 Vágóhíd Zrt. 7700 Mohács, Pick Márk u. 1.	07/29/2019	1360	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 .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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	X
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

15) The establishment's Hazard Analysis identifies fecal and ingesta as likely to occur, with no associated Critical Control Point to control the identified hazard it has only a CP. Establishment rely on the Government inspection for zero tolerance identification. Government inspectors conducts 100% zero tolerance checks on carcasses at the final rail inspection point. It should be noted that the establishment previously had zero-tolerance a CCP but changed it since they were not finding fecal and ingesta on a recurring basis. Establishment had no support for this decision. The establishment's written HACCP Plan does not include procedures or frequency of the verification procedure of Direct Observation.

36) Separation of USA Product: Establishment was not following their program and had other product not intended for the United States stored in USA designated area

39) Carcass Chain from cooler to transfer area in the fabrication room had rust (over exposed carcasses) Previously identified by CCA however the establishment did not take immediate action but delayed taking any action until late August 2019

45) Blue plastic product crates (many) that hold exposed raw pork product were observed to be cracked and frayed causing possible product contamination with foreign material

46) Fabrication Room: Wizard knife and exposed product container were to close to the floor with the potential for cross contamination from boots and floor debris. Fabrication Room: gray bin holding rib sections of raw pork product was found to have fecal/ingesta contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/29/2019

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/ 2 /2020. Budapest 6th January 2020

For Dr. Michelle Catlin
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 the findings of the on-site equivalence verification audit conducted by the USDA Food Safety and Inspection Service (FSIS) from July 22 through August 2, 2019.

Dear Dr. Catlin,

I would like to thank you for sending us the draft final report of the audit conducted in Hungary from July 22 through August 2, 2019.

Following the audit the establishments started to develop their detailed action plans where needed, and also have put in place those immediate actions that needed to be implemented without any delay. The verification audits by the local (DGO, CGO) and by the central competent authority (NFCSO) are now complete, except for Est. HU 23 EK. According to the reports, the identified shortcomings have been remedied in all establishments since the audit, and the conditions for the production of safe and wholesome pork products as per FSIS's standards are granted. In the case of establishment HU 23 EK, supervisory review by the NFCSO is still to be performed, possible restitution of this establishment is pending the result of NFCSO's review. We have already informed you on the action plan and the immediate corrective actions taken by Est. HU 1360 EK and their verification by the NFCSO therefore these are not covered in this letter.

As with the systemic finding related to the routine government chemical residue sampling, Hungary operates its chemical residue monitoring program accordingly to the relevant EU law. Since this is a monitoring sampling program, it is not designed to prevent the use of an individual non-compliant carcass for food production. However, it is already a

common practice not to use such carcasses for any export related production and this will be further enforced in the form of an official instruction.

All slaughtering establishments have put in place measures to ensure that zero tolerance requirements are met for carcasses concerning the presence of fecal material, ingesta, and milk prior to entering the chill cooler. Offline verification of these requirements by the competent authority in a documented manner is now ensured.

Findings related to the HACCP system have been remedied, the establishments have updated their HACCP plans and the modifications have been verified by the competent authority.

As a summary, NFCSO conducted an audit in all but one (Est. HU 23 EK) establishments visited during the FSIS audit and have concluded that the measures taken by the establishments and by the local competent authorities are satisfactory and are able to resolve the identified shortcomings.

The supporting documentation, together with a courtesy translation, is provided in the form of attachments. This also includes the actions taken regarding the findings noted in the individual establishment audit checklists.

I hope that the measures taken both by the competent authority and by the establishments will be deemed satisfactory.

Yours sincerely,

Agrárminisztérium Helyettes Államtitkár * 1. *

Lajos Bognár DVM

H-1052 Budapest, Apáczai Csere János u. 9., Phone: (+36 1) 795-3785, Fax: (+36 1) 795-0564

Procedure	CCP number	Hazard description	Critical limits	MONITORING				Corrective action
				MONITORING Procedures	Verification	Person in charge	Document	
Sv/12	CCP/1B	Biological hazard: fecal contamination of the carcass during the trimming, tying and removal of the intestines	Fecal contaminat ion free surfaces. Zero-tolerance on feces contamina-tion.	The employee in charge executes a visual assessment of every single carcass. See SOP. Chapter 3.	The plant manager controls the assessment done by the person in charge two times per shift. The quality control manager executes weekly, unexpected controls of the appropriateness of the control by the plant manager and/or the correctness of the documentation.	Employee	Hygienic control of pig carcasses with zero-tolerance on fecal contamina-tion. Sv / CCP1B	The employee must execute a visual assessment of both sides of the pig carcass (side with skin and side with meat) for fecal contamination. The assessment needs to be thorough and a replacement must always be ensured in case the employee is sick or any other issue occurs. The place of the assessment needs appropriate lighting. This is a compulsory requirement. The result of the assessment must be recorded on the relevant forms. The employee who executes the assessment, as well as their replacement, needs to receive a training every year. In case the employee finds any trace of fecal contamination on the carcass they stop the cutting process and alert the plant manager who gives immediate order for a pause. The cause of the contamination must be identified (faulty equipment, machine, inattention of an employee, etc). A full technological, technical and human control must be executed. Cutting can only restart once the technical or human problem has been satisfactorily and permanently resolved. Fecal decontamination is done by steam-vacuum sanitizing, carried out by an appointed and trained specialist under the plant manager's control. Carcasses processed during the contamination period must be handled separately and can only be used for domestic, heat-treated products.

Pre-shift Veterinary Inspection

Time: 28/10/2019 5am – 6am

The assessment is based on checking the following areas:

Sv. 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10
Fd.: 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11
S.: 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14
F.: 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8
Exp.r. 7.1, 7.2, 7.3, 7.4

Verification of cleaning before the shift starts: SATISFACTORY
UNSATISFACTORY

Deficiencies: ---

Measures taken: ---

Second verification: ---

Verification of production hygiene during shift: SATISFACTORY
UNSATISFACTORY

Deficiencies: The cutter is not cleaned during the lunch break

Measures taken: Ordering immediate cleaning

Second verification: Satisfactory

PLANT CLEANING:
SATISFACTORY NEEDS CORRECTION UNSATISFACTORY

Documentation, record keeping, implementation: **SATISFACTORY UNSATISFACTORY**

Deficiencies: ---

Measures taken: ---

Second control: ---

SSOP: **SATISFACTORY NEEDS CORRECTION UNSATISFACTORY**

HACCP: **SATISFACTORY UNSATISFACTORY**

EVALUATION: SATISFACTORY NEEDS CORRECTION UNSATISFACTORY

Received by Controlled by

Signature Signature

ÉRKEZETT
2019 DEC 04.
Sorszám: Helyben!

VESZPRÉM MEGYEI
KORMÁNYHIVATAL
PÁPAI JÁRÁSI HIVATAL

VE/21/2019 DEC 04.
00098-29/2019.

Ügyiratszám: VE-05/EBA/0022-240/2019

Ügyintéző: Dr. Kasper László

Telefon:89/313-014

Tárgy: Teljes körű csekklistás negyedéves USA ellenőrzés

Hiv. szám:

Készült : Pápai Hús KFT 8500 Pápa,Kisfaludy u. 2.

Jelen vannak:	Dr Kasper László	hatósági állatorvos
	Dr. Holló Zsuzsa	hatósági állatorvos
	Sebestyén Krisztián	minőség felügyeleti főosztályvezető
	Benedek Szabolcs	műszaki igazgató helyettes
Időpont :	2019.december 04.	

Az üzem működési engedélyének száma: VEI/001/00235-7/2017.

Korábbi USDA/FSIS (2019 július 31.) ellenőrzés helyesbítő intézkedéseinek visszaellenőrzése:

1. A vállalkozás módosította a monitoring megfigyelés verifikálására vonatkozó eljárásrendjét, melyben biztosítja a megfelelő előírt verifikációt és dokumentációt. (1. melléklet)
2. A zero faecal tolerancia eltérésének azonosítására új eljárásrendet dolgozott ki a vállalkozás, mely szerint már egy darab faecal szennyeződés esetén is kivizsgálásra és dokumentálásra kerül az eltérés oka. Helyesbítő intézkedés történik minden esetben
3. A sonka kiszedő helyiség pergő festéke eltávolításra került, a felületet újra festették. ntézkedési terv készült a vállalkozás részéről a hosszú távú műszaki megoldásra (a meglévő világítótestek lebontása, kábelcsatlakozások kiépítése az új álmennyezet alatti világítás számára. 3-5 cm hőszigetelt panel álmennyezet készítése az érintett felületet határoló födémgerenda alsó síkjában, a gerenda szabad oldalfelületének panelburkolása. A meglévő világítótestek visszaszerelése. A tervezett műszaki megoldáshoz a szükséges anyagokat megrendelték.)
4. A kiegyenlítő hűtőben a kondenzációt megszüntették, az elpárologtatókat összekötő, egymás felett haladó hűtési vezetékek alumínium héjazatán képződött kondenzátum

NEM 1061HN

elvezetésére a csővezetékek alá műanyagból készült kondenzátum gyűjtő csatorna került felszerelésre, az elpárologtatók közösített olvadékvíz lefolyójához csatlakoztatva lett.

5. Nincs repedt húsos kocsi, a repedt húsos kocsik javítása folyamatos, szükség szerint selejtezésre kerültek. 100 db új húsos kocsi beszerzése folyamatban van
6. A sonkaüzemben a csővezeték új kiépítése megtörtént, így takarítása megoldott, a régi használt átlátszó vezeték cseréje megtörtént.
7. A nyitott csővezetékek lezárása megtörtént
8. A ládatartók áthelyezése és magasítása megtörtént.
9. A rozsdásodásokat mechanikusan eltávolították, a kötőelemeket intézkedési terv szerint rozsdamentesre cserélik. A rozsdafoltok folyamatos eltávolítása bekerült a karbantartási tervbe.

Pápa,2019 december 04.

PÁPAI HÚS KFT.
PÁPA

Sebestyén Krisztián
minőségfelügyeleti főosztályvezető

Dr. Holló Zsuzsa
hatósági állatorvos

Dr. Kasper László
hatósági állatorvos

Élelmiszerlánc-biztonsági és Állategészségügyi Osztály
8500 Pápa, Fő u. 12.
telefon: 89/795-093, fax: 89/795-100, e-mail: papa.elelmiszer@veszprem.gov

Findings and summary of the official inspection report HU 6

15) The establishment does not identify procedures or frequency of the verification Direct Observation of monitoring. This is a repeat finding at this establishment.

The establishment modified its procedure regarding the verification direct observation of monitoring, in which the required verification and documentation is ensured (Attachment 2)

20) The establishment's HACCP Plan does not include procedures to identify the cause or measures to prevent recurrence of the deviation of zero tolerance fecal. This is a repeat finding at this establishment.

The establishment developed new procedure to identify the deviation of zero tolerance on fecal contamination. According to the procedure, the cause of the deviation must be investigated and documented after a single contaminated carcass and corrective measures must take place in each case. (Attachment 1)

39) Flaking paint in ham removal room with paint flakes on work areas.

Flaking paint has been removed, the surfaces has been repainted. An action plan was prepared by the establishment for a long term solution. (electric re-design of the current lighting arrangements with the removal of the lamps, relocation of cable connector boxes for the new lighting arrangements under a new suspended ceiling – installation of a 3-5cm thick, thermally insulated suspended ceiling at the lower level of the joist confining the affected area; covering the surfaces on the side of the joist; reinstallation of lamps) An order has been placed by the company for the construction materials needed for the re-fit.

41) Beaded condensation above products in coolers which had dripped on product carcasses.

Condensation has been eliminated, the condensation accumulating on the aluminium covering of the cooling pipes connecting the evaporators is now collected in a newly installed plastic drainpipe system designed specifically for the collection of condensation water; the drainpipe is channelled into the existing condensation water drain of the evaporators.

45) Stainless product bins were cracked. Piping for cure solution could not be disassembled to allow for inspection/adequate cleaning. Rusted gambrels, rusted overhead structure (rails, brackets, etc.) in areas including slaughter floor, deboning area, curing area, ham area.

There were no cracked bins at the time of the inspection. Cracked bins are being repaired continuously, discarded when necessary. The purchase of 100 new bins is in progress.

46) Rusted areas were over exposed product, rail dust/dirt was also observed on product and product contact surfaces. Product tubs stored near the floor and next to worker stands which could contact boots.

Rusting was removed mechanically. Fittings will be replaced to stainless fittings according to action plan. Continuous removal of rust is now included in the maintenance plan. Storing place for product tubs are relocated and raised.

50) Government inspection personnel do not conduct or document verification of operational sanitation on a daily basis.

We have identified that this finding is probably based on a misinterpretation occurred during the audit. Conducting and documenting the verification of operational sanitation is in fact performed on a daily basis. Indeed, the header of the relevant checklist translates to "Pre-operational veterinary check", but besides the pre-op inspection it also includes a section for hygiene inspection during operation. (Attachment 2)

Non-compliances noted in the draft final audit report of USDA FSIS audit, their corrective measures and their official verifications in Establishment HU 7 EK

No. of finding in draft final audit	Description of non-compliance	Action taken by the establishment	Deadline in the action plan	Date of verification inspection	Notes by the authority
14	The establishment's written HACCP Hazard Analysis identified microbiological hazards that were reasonably likely to occur however, they did not identify lethality controls (Salmonella) for dry curing RTE salami (Sausage) processing steps although the processes had a scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.	Lethality control parameter established in USA-HACCP for the relevant CCP	2019.11.28	2019.12.02	Critical limit: aw≤0,85
22	The FSIS auditors observed that the establishment does not include/record the time of the event for the completion of verification (record review, direct observation).	Recording the time of completion of the CCP verification	2019.11.28	2019.12.02	

36	Establishment Lm Control Program did not include a listing of all product contact sites; during the establishment tour FSIS auditors observed additional contact sites of employee aprons, and employee work coats.	Integrate the sampling of employee aprons and work coats in the sampling plan.	2019.11.28	2019.12.02	
39	Overhead rails and equipment used in the salami stuffing area were observed to be rusted.	Inspection of overhead rails in the salami stuffing area, mechanical removal of rust, painting of surfaces.	2020.01.31	in progress	
39	Peeling paint and overhead dust-dirt observed outside of the smoke rooms.	Inspection of overhead rails and it's surrounding near the smoke rooms area, mechanical removal of rust, painting of surfaces, repairing plaster on walls	2020.01.31	in progress	
45	In the deboning area; conveyor belt scrapers observed in deteriorating condition	Replacing conveyor belt scrapers	2020.01.31	in progress	
45	In the deboning area; residue observed in stainless product tubs, cubing/flaking machine observed to have heavy wear on metal parts with metal missing due to rubbing of parts	Restoration of the cubing machine	2020.02.28	2019.12.02	
10, 45	Establishment does not conduct a complete clean-up (to include complete disassembly of equipment) prior to production of product for the United States. Equipment was not disassembled to the extent necessary to allow for adequate cleaning, or inspection by the government inspector.	Training of maintenance workers.	2019.11.28	2019.12.02	If U.S. production takes place on the following day, the machinery must be disassembled to a degree that allows for the complete cleaning of the equipment and can be assembled again after pre-operational inspection by the competent authority.

45,46	Residues from previous operations were observed in the following areas due to lack of disassembly and complete clean-up; salami stuffing area, RTE product sorting area, and RTE product packaging area. Exposed product in cooler was observed to have multiple areas of rail dirt, grease contamination.	Repeated training of the workers on the entire salami line.	2019.12.31	in progress	On the instruction of the local competent authority the contaminated material was immediately separated, and restrained from being used for U.S. production.

5th December 2019, Szeged.

Márton Hegyi, DVM
official veterinarian
sk.

Declaration on the corrective measures by the establishment, regarding the non-compliances identified during FSIS's audit on 25 July, 2019.

HU 23 EK – Hungary Meat Kft.

7, 10.) The establishment SSOP program does not include procedures to be conducted during operations to prevent contamination or adulteration of product. Additionally, the establishment's SSOP program does not include a frequency of monitoring of operational sanitation.

According to 9 CFR416 Sanitation, an SSOP manual has been compiled, and was issued on 30th August, 2019. This includes the detailed description of procedures to prevent the contamination or adulteration of the product – both pre-operation and during operation, as well as the description of control procedures, including their frequency and the responsible employees. The controls described in the SSOP manual are performed and documented as of 2 September 2019.

14) The establishment's Hazard Analysis identifies a biological hazard (microbiological--Salmonella) as likely to occur, with no associated Critical Control Point to control the identified hazard.

An updated HACCP plan was issued on 30th August 2019 including a new CCP1. Within the control of surface contamination of carcasses takes place the handling and safe separation of carcasses with faecal contamination in order to prevent such carcasses from being used or U.S. export. The related corrective actions are in place for the new CCP and are implemented as of 2 September 2019. As an additional measure, the carcasses forwarded to cutting are check one more time and if necessary, sent to a separation line for corrective measure to be performed.

15) The establishment's written HACCP Plan does not include procedures or frequency of calibration of thermometers used for monitoring of CCP critical limit. The establishment's written HACCP Plan does not include procedures or frequency of the verification procedure of Direct Observation.

The new HACCP plan issued on 30 August 2019 includes the calibration process of thermometers as well as the description of the verification process.

36) During the establishment tour, FSIS auditors observed that the competent authority had one inspection person stationed at the end of the viscera-head-carcass inspection area who served as the final rail inspector. No additional government verification of carcass dressing or zero tolerance occurs prior to carcasses entering the chill cooler. During the establishment tour, the FSIS auditors observed one carcass in the cooler with a large area of yellow staining from the evisceration process.

Refers to the competent authority. This component is to be verified by NFCSO's supervisory review in the future.

39) Overhead rails with heavy buildup of grease and dirt.

To avoid overgreasing of the overhead rails, greasing of the overhead rails can only be performed by dedicated maintenance workers during weekend maintenance in the minimum possible extent. The lubricant used is qualified as food grad according to 21 CFR 178.3570 Lubricants with incidental food contact. The occasional buildup of excess lubricant is removed on a weekly basis by the dedicated cleaning staff members. Carcasses are checked once again when entering the cutting room to detect any occasional contamination with grease from the rails.

41) Areas of beaded condensation in coolers above carcasses.

The cooling operations and equipment in the carcass coolers have been reviewed and several modifications were implemented as result. The coolers are turned on during the cleaning operations, well in advance of storing in the carcasses, thus preventing condensation. Occasional condensation is removed with a special tool designed for the purpose, with dedicated staff. The production process has been reorganized. Slaughtering begins later during the day while boning begins earlier. As a result, the cooling down of the carcass coolers can begin earlier to minimize condensation and since carcasses left the coolers earlier due to the modified working schedule, there is also more time available for cooling down the chamber after the cleaning operations. Implementing these measure eliminated the issue of condensation in the coolers.

46) Numerous carcasses within the cooler and entering into the deboning area were observed to be affected by rail dirt-grease. CCA indicated because of the known problem with rail dirt-grease, the establishment has instituted the use of a person assigned to identify affected carcasses. FSIS auditors observed that this designated establishment employee was unable to identify all affected carcasses. Additionally, affected carcasses were observed to routinely come in contact with non-affected carcasses thereby causing cross contamination.

The speed of the line forwarding the carcasses from the coolers to the deboning area has been reduced to avoid congestion of the carcasses thus preventing possible cross contamination. The reduced line speed allows for the thorough inspection of each individual carcass in order to detect any non-compliance and to separate the contaminated carcasses. Should the boning line stop for any reason, the employee assigned to identify the affected carcasses is to shut down the line supplying the carcasses from the coolers immediately.

TRANSLATION

BÁCS-KISKUN Regional Government Office

Food-Chain Safety and Land Register Main Department
Food-Chain Safety and Animal Health Department

File number: BK/EBAO/ 10 -32 /2019.
Official in charge: Dr. Drozdik Ferenc

Subject: USDA/FSIS control
Attachment: 6 + 8 pieces

To: Dr. György Pleva
Director

Food-Chain Safety Office
Food and Crop Safety Head Office

Budapest
Keleti Károly u. 24.
1024

Date: 05.12.2019, Kecskemét

Dear Director,

With reference to the case nr. 5200/1158-80/2019, please find enclosed the documents regarding the report on the USDA/FSIS audit dated on 25.07.2019.
I certify that an inspection was carried out by the representatives of the Township Office of Kiskunfélegyháza and Bács-Kiskun Regional Government Office, on 04.12.2019. An official report has been written on the inspection, which you will find enclosed.
In the enclosed document, Hungary Meat Kft. listed the corrective actions that have been implemented following the observations made in accordance with the "Foreign Establishment Audit Checklist", which, in our view, allow the factory's proper operation in line with the USDA/FSIS requirements.
The enclosed report by the Township Office of Kiskunfélegyháza includes the observations concerning the comments about the state control.

Sincerely,

Bács-Kiskun Megyei Kormányhivatal
HU 331-0000
megyei irányítószám

Kovács Ernő
Government
Representative in charge

Dr. Drozdik Ferenc
Head of
Department

6000 Kecskemét, Halasi út 34. Pf.: 155
email: bacs-elelmiszer@bacs.gov.hu
Food-Chain Safety and Land Register Main Department
Ph: 76/896-341
Fax: 76/998-347

ACTION PLAN

Subject: 2019. III. Action plan following the inspection of the quarterly USDA control (02.10. 2019)

Location: Pick Szeged Zrt. Alsómocsolád **Date: 02. 10.** 2019
Action plan created by: Tünde Miklós

Recipients: All concerned
Measures, tasks:

Task	Person in charge	Deadline	Risk	Control (signatures)
The repaired part of the rubber sealing around the glass of the door between the expedition and box opening room is not adequately tight. ■ The rubber around the glass needs to be sealed.	Tamás Bágyi	18. 10. 2019	3	*signature*
Small spots of filth embedded in the frozen bacon. NMF 2019-007396 ■ Reporting the problem to MCS.	Tünde Miklós	08. 10. 2019	1	*signature*
Following the ripening, the product touched the coat of the worker placing the products into the crates. ■ Wearing an apron is compulsory. Introducing sampling.	Adrienn Györki Gáborné Téczeli	18. 10. 2019	3	*signature*
Signs of water leakage and small spots of mold on the ceiling in the packaging material storage room. ■ Repairing and painting the ceiling.	Tamás Bágyi	18. 10. 2019	3	*signature*
1-2 cm wide gap between the panels in the corner of the packaging material storage room. ■ Gaps need to be closed.	Tamás Bágyi	18. 10. 2019	3	*signature*
Bed bugs in the insect trap at the door of the packaging material storage room. ■ Insect control is necessary.	Gáborné Téczeli	18. 10. 2019	3	*signature*
The empty (used) boxes for bar product storage that were to be washed, were kept in the corridor. In one of them, the paper on the bottom and the box itself was covered with green mold.	Adrienn Györki	18. 10. 2019	3	*signature*

ACTION PLAN

■ Boxes need to be dried inside before usage. Employee training needed.				

Risk: 1 Inside production area, open product zone
2 Inside production area, closed product zone
3 outside production area

Measures: Risk 1: Immediately
Risk 2: Within one week
Risk 3: Upon schedule

Rendben' Miklós Tünde

Written by:

Signautre
Tünde Miklós
Quality Manager

Approved by:

Némethné Pálfy Mária
Production Director – Meat production

Alsómocsolád, 08. October 2019

MCS Abatoir Zrt. Bonafarm Group strategic partner, Raw material supplier of Pick Szeged Zrt.

Action plan of Establishment HU 86 EK following FSIS audit

36.) Establishment Lm Control Program did not include all product contact sites in their list of sites to be tested; that come in contact with product; during the establishment tour FSIS auditors observed an additional contact site of employee aprons, and employee arm plastic wrap.

Task	Responsible	Deadline	Risk	Verification
Protective clothes worn by personnel loading the salami type products into crates following maturation can come into contact with product • Wearing an apron is mandatory • Introduction of sampling	Györki Adrienn Téczeli Gáborné	2019.10.18.	3	

Risks:

1- within production area – “open product”
2- within production area – “closed product”
3- outside production area

Laboratory Test Report

Customer details:

Customer's name:	Pick Szeged Zrt.
Customer's address:	6725, Szeged, Szabadkai ut 18
Name of the plant:	Alsomocsolád Plant
Plant address:	7345, Alsomocsolád, Alsomocsoládi ut 2.
Submitted by:	Gáborné Téczeli

Sampling details:

Sample taken by:	Customer		
Date of sampling:	**Date of arrival**	**Start of analysis**	**End of analysis**
14.10.2019	14.10.2019	14.10.2019	21.10.2019

Sample Reference nr	2019/P/20810 Filling machines 5, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-1	Sample identification:		259762

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019 / P / 20811 Grinding machine, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-2	Sample identification:		259763

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20812 Cutter edge, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-3	Sample identification:		259764

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20813 Frozen meat cutter, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-4	Sample identification:		259765

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20814 Box, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-5	Sample identification:		259766

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20815 Safety glove 1, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 personal hygiene swabs			
LOT number	4-6	Sample identification:		259771
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20816 PVC safety apron, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 personal hygiene swabs			
LOT number	4-7	Sample identification:		259772
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20817 Safety gloves 3 checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 between shifts hygiene swabs			
LOT number	4-8	Sample identification:		259773
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20818 Portioning line, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 between shifts hygiene swabs			
LOT number	4-9	Sample identification:		259774
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20819 Filling machine alginate, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 between shifts hygiene swabs			
LOT number	4-10	Sample identification:		259775
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20820 Clipper 6, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 between shifts hygiene swabs			
LOT number	4-11	Sample identification:		259776
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20821 Smoking machine, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Plant 2.		Customer id:	PICK18719
Name of the sample:	9000004 between shifts hygiene swabs			
LOT number	4-12	Sample identification:		259777
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20822 Glove 2, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing-Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 personal hygiene swabs			
LOT number	4-13	Sample identification:		259781
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20823 Sleeve protector, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing-Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 personal hygiene swabs			
LOT number	4-14	Sample identification:		259783
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20824 Overalls, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing-Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 personal hygiene swabs			
LOT number	4-15	Sample identification:		259784
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20825 Packaging machine R/530/ 3, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing-Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-16	Sample identification:		259785
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20826 Slicing machine, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing-Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 cleaning hygiene swabs			
LOT number	4-17	Sample identification:		259786
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20827 Slicer belt, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing- Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 Cleaning hygiene swabs			
LOT number	4-18	Sample identification:		259787
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20828 Knife sharpener, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing- Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 Cleaning hygiene swabs			
LOT number	4-19	Sample identification:		259788
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20829 Side wall, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing- Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 Cleaning hygiene swabs			
LOT number	4-20	Sample identification:		259789
Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Sample Reference nr	2019/P/20830 Packaging table 4, checking 2 production sites for Salmonella Listeria moncytogenes. Sampling location: Slicing- Packaging area		Customer id:	PICK18719
Name of the sample:	9000004 Cleaning hygiene swabs			
LOT number	4-21	Sample identification:		259790

Analyzed parameter	Analysis method	Result	Reference	Assessment
Salmonella spp.	MSZ EN ISO 6579-1:2017	negative	on 100 cm^2	Appropriate
Listeria monocytogenes	MSZ EN ISO 11290-1:2017	negative	on 100 cm^2	Appropriate

Remarks: Results in the laboratory test report only concern the provided samples.
Claims about the test results are only accepted **within 5 days** after reception of this report.
Without a written authorization by the laboratory, the report can only be copied in its full length, without any modifications.

Referral standard, laws:
4/1998. (XI.11.) Decree by the Ministry of Health

Zsuzsanna Kárnyáczki
Laboratory Director

Eurofins Food Analytica Kft
5700 Gyula, Henyei Miklos u. 5.
VAT nr: 13792198-2-044

SIGNATURE

..n bíh
tE>rmőfökltől
az asztalig

Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH*l-1656/2015 számon akkreditált
vizsgá lóla boratórium.

1095 Budapest Mester utca 81.
Te!: (1) 456 3010
Fax:(1)2156851
E-mail: eli@nebih.gov.lm
www.nebih.gov.hu

E2019-ETBI-016119

ANALYSIS PROCEEDINGS

File number:	**A2019-ETBI-011738**
Sampling authority:	Food Safety and Veterinary Department at Komlo Township Office of Baranya Region Government Office
Sampling Proceedings number	501613
Samples taken by:	dr. Zoltán Szemenyei
Date of sampling:	2019.10.07
Remarks:	

Laboratory identification number of the sample:	**M2019-ETBl-011738/01**	
Name of the item:	**USA Báthory csemege szalámi (USA Báthory deli salami)**	**Item id:** 9242
Best Before and Use-By Dates:		
Sample signalization:	3. Type of sample: salami	
Name and address of the sample provider person/company	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verify export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag	
Quantity of the sample	600 g, sample basis: 3985.6 kg	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	**Result (quantifying uncertainty)**	**Method**
Listeria monocytogenes Starting of the test: 10.10.2019	Negative /25 g	USDA/FSIS MLG 8.10 2017
Salmonella spp. Starting of the test: 10.10.2019	Negative /325 g	MSZ EN ISO 6579:2006 (withdrawn standard)

Price estimate (M2019-ETBI-011738/0l)

Title	**Price/unit**	**Quantity**	**Net amount**
Showing the presence of listeria monocytogenes (ÉTbI)	5780	1	5780
Proving the presence of Salmonella spp. and defining their number	5720	1	5720
Analyzing samples taken via print, swab or scraping techniques for hygienic control. VAT per substrate.	2610	11	28710

Laboratory identification of the sample:	**M2019-ETBl-011738/02**	
Name of the item:	Packaging line, during operation FCS	Item identification: -

blh
tE'rmőföldtől
az asztalig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH-1-1656/2015 számon akkreditált
vizsgáló la boratórium.

1095 Budapest Mester utca 81.
Tel:(1)4563010
Fax:(1)2156851
E-mail: eli@nebih.gov.hu
www.nebih.gov.hu

Best Before and Use-By Dates:	
Sample signalization:	1. Type of sample: hygienic swab
Name and address of the sample provider person/company	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2
Aim of the sampling:	Verifying export conditions to the USA Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge
Quantity of the sample:	1 piece as a basis for sampling:-
Date of the reception of the sample:	09.10. 2019
Remarks:	

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Listeria monocytogenes Start of the test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-0ll738/02)

Title	Price/unit	Quantity	Net amount

Laboratory identification of the sample:	**_M2019.,,ETBb011.738/03.**	
Name of the item:	Packaging cap, during operation **FCS**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	2. Type of sample: hygienic swab	
Name and address of the sample provider person/company	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10.2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimates (M2019-ETBI-0ll738/03)

Title	Price/unit	Quantity	Net amount

n bíh
termóföldtől
az asztalig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH-1-1656/2015 számon akkreditált vizsgálólaboratórium.

1095 Budapest Mester utca 81.
Tel:(1)4563010
Fax:(1)2156851
E-mail: eli@,nebih.gov.hu
www.nebih.gov.hu

Laboratory identification of the sample:	**M2019-ETBI-Ol l 738/04**	
Name of the item:	**Employee's safety glove during operation FCS**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	3. Type of sample: hygienic swab	
Name and address of the sample provider person/company	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling	
Date of the reception of the sample:	09.10.2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-0ll738/04)

Title	Price/unit	Quantity	Net amount

Laboratory identification of the sample:	**M2019-ETBI-011738/05**	
Name of the item:	**Apron during operation FCS**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	4. Type of sample: hygienic swab	
Name and address of the sample provider person/company	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling	
Date of the reception of the sample:	09.10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-011738/05)

Title	Price/unit	Quantity	Net amount

blh
termőföldtől
az asz,alig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH-1-1656/2015 számon akkreditált vizsgálólaboratórium.

1095 Budapest Mester utca 81.
Tel:(1)4563010
Fax:(1)2156851
E-mail: eli@nebih.gov.hu
www.nebih.gov.hu

Laboratory identification of the sample:	**M2019-ETBI-011738/06**	
Name of the item:	**Inside of the box during operation FCS**	**Item identification: -**
Best Before and Use-By Dates:		
Sample signalization:	5. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag 1 scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

VIZSGÁLATI EREDMÉNYEK

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (l\12019-ETBI-011738/06)

- Title -	Price/unit	Quantity	Net amount
Tracking the presence of listeria monocytogenes (ÉTbI)	5780	1	5780

Laboratory identification of the sample:	**M2019-ETBI-011738/07**	
Name of the item:	Bottom of a box during opearation, sample from the environment	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	6. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag 1 scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH-1-1656/2015 számon akkreditált
vizsgálólaboratórium.

1095 Budapest Mester utca 81.
Te!:(!) 456 3010
Fax:(1)2156851
E-mail: eli@nebih.gov.lm
www.nebih.gov.hu

Price estimate (M2019-ETBI-011738/07)			
Title	**Price/Unit**	**Quantity**	**Net amount**

Laboratory identification of the sample:	**M2019-ETBI-0ll738/08**	
Name of the item:	**Pallet during operation, environment sample**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	7. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	**Pick Szeged Szalámigyár és Húsüzem Zrt.** 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09.10. 2019	
Remarks**:**		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDNFSIS MLG 8.10 2017

Price estimate (M2019-ETBI-011738/08)			
Title	**Price/Unit**	**Quantity**	**Net amount**

Laboratory identification of the sample:	**M2019-ETBl-011738/09**	
Name of the item:	Side wall during operation, environment sample	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	8. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út I8	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09. 10. 2019	
Remarks**:**		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDNFSIS MLG 8.10 2017

1095 Budapest Mester utca 81.
Tel:(1)4563010
Fax: (l) 215 6851
E-mail: eli@nebih.gov.hu
www.nebih.gov.hu

Price estimate (M2019-ETBI-011738/09)			
Title	**Price/Unit**	**Quantity**	**Net amount**

Laboratory identification of the sample:	**M20I9-ETBI-011738110**	
Name of the item:	**Benches during operation, environment sample**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	9. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-011738/10)			
Title	**Price/Unit**	**Quantity**	**Net amount**

Laboratory identification of the sample:	**M2019-ETBI-0ll738/11**	
Name of the item:	**Lavatory, during operation, environment sample**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	10. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method

Start of listeria monocytogenes test: 10. 10. 2019	Negative/surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-011738/11)			
Title	**Price/Unit**	**Quantity**	**Net amount**

Laboratory identification of the sample:	**M2019-ETBI-011738/12**	
Name of the item:	**Floor drain, during operation, environment sample**	Item identification: -
Best Before and Use-By Dates:		
Sample signalization:	11. Type of sample: hygienic swab	
Name and address of the sample provider person/company:	Pick Szeged Szalámigyár és Húsüzem Zrt. 6725 Szeged, Szabadkai út 18	
Place of the sampling:	PICK SZEGED ZRT. HUSÜZEM 7345 Alsómocsolád, Alsómocsoládi út 2	
Aim of the sampling:	Verifying export conditions to the USA	Monitoring code:
Packaging of the item and the sample:	Plastic bag scrubbing sponge	
Quantity of the sample:	1 piece as a basis for sampling:-	
Date of the reception of the sample:	09. 10. 2019	
Remarks:		

TEST RESULTS

Test parameters	Result (quantifying uncertainty)	Method
Start of listeria monocytogenes test: 10.10. 2019	Negative / surface with patterns	USDA/FSIS MLG 8.10 2017

Price estimate (M2019-ETBI-011738/12)			
Title	**Price/Unit**	**Quantity**	**Net amount**

blh
termőföldtől
az asztalig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Élelmiszerlánc-biztonsági Laboratórium Igazgatóság
Mikrobiológiai Nemzeti Referencia Laboratórium
A NAH által NAH-1-1656/2015 számon akkreditált vizsgálólaboratórium.

1095 Budapest Mester utca 81.
Tel:Jl)4563010
Fax:(1)2156851
E-mail: eli@nebih.go\•.hu
www.nebih.gov.hu

Remarks:
*Non accredited method.
Samples and test results are treated as confidential.
The test results are based on the samples and sample items which were sent in or taken.
Partial copies of the Analysis Proceedings are not allowed to be made without the laboratory director's permission.
Test result are to be referred to by the reference number of these proceedings.
In each case, the laboratory interprets the quantifying uncertainty according to the Eurachem/CITAC Guide CG4/E.5.6. l. point (x ± U).

Budapest, October 15. 2019.

dr. Sréterné dr Lancz Zsuzsanna
Laboratory Director

MINISTRY OF
AGRICULTURE

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

Ref: ÉlfF/355- 2 /2019. Budapest 24th September 2019

For Dr. Michelle Catlin
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:

Dear Dr. Catlin,

I have received your letter dated on 10 September, 2019 on the systemic finding regarding the lack of requirements and inspection verification procedures for online and offline government zero tolerance verification.

As a response to this systemic finding, the National Food Chain Safety Office issued a set of requirements for the County Government Offices and for the eligible establishments by way of its letter No. 5200/1158-66/2019.

Zero tolerance on the visible surface contamination (fecal, milk, or ingesta) must be verified by the competent authority according to the following parameters:

- The competent authority is obliged to inspect each carcass on the absence of visible surface contamination after the point where the establishment performed its own check for zero tolerance, which may have included corrections as well;
- Visible surface contamination must not be present on the carcasses after the final step of the official post mortem inspection – the inspection of internal and external surfaces of the carcass;
- In such cases when the applied technology in a given establishment does not make it possible to ensure the fulfillment of the abovementioned conditions, the corrections must be performed on the separation line. Carcasses that have been forwarded to such separation line are to be excluded from U.S. export;
- The competent authority is to document the inspections performed, including the carcasses sent to the separation line.

H-1052 Budapest, Apáczai Csere János u. 9., Phone: (+36 1) 795-3785, Fax: (+36 1) 795-0564

Establishments must fulfill the following requirements to ensure zero-tolerance on visible surface contamination:

- Overfeeding of the live animals intended to be slaughtered must be avoided;
- Slaughterhouse equipment must be kept in a good condition, with particular emphasis on the rectum cutting tool;
- The most experienced workers shall perform those steps, where occurrence of visible surface contamination is possible such as rectum cutting, evisceration. In the case of a higher line speed, workers must be rotated to reduce the chance for mistakes;
- The rectum has to be closed either by a bag or by way of tying after being cut;
- The carcasses must be inspected by the designated worker(s) after evisceration looking for visible surface contamination;
- When visible surface contamination occurs, it must be corrected by the designated worker(s);
- The inspections performed must be documented, including the number of the carcasses detected with visible surface contamination
- Even after only one contaminated carcass, a root cause analysis must be performed;
- All requirements regarding the CCPs on the zero tolerance on visible surface contamination must be included in the HACCP plan of the establishment.

I hope that the above will also help in clarifying the responsibilities of both the establishment employees and the government inspectors and the measures will be deemed as appropriate to correct the identified systemic finding.

Please also find enclosed a courtesy translation of the corrective actions that have been performed in the individual case of Est. No. HU 1360 EK (MCS Vágóhíd Zrt.) and their verification by NFCSO. The eligibility of the establishment to produce meat raw materials for U.S. export has been restituted by the NFCSO.

Yours sincerely,

Lajos Bognár DVM

Agrárminisztérium Helyettes Államtitkár * 1. *

Attachment: Findings of the supervisory inspection by NFCSO at Est. HU 1360 EK

H-1052 Budapest, Apáczai Csere János u. 9., Phone: (+36 1) 795-3785, Fax: (+36 1) 795-0564

Attachment 1.

NFCSO instructed the establishment on 30 July 2019 by way of its letter No. 5200/1158-59/2019 to take corrective measures regarding the identified shortcomings and prohibited the production of raw materials for the purpose of U.S. export pending the verification of the corrective measures by the NFCSO. The findings of the inspection carried out by the NFCSO are as follows.

- SSOP checklists have been modified and supplemented as of 6 August, 2019 with the issuance of a new version (V.4). The changes were communicated to the plant managers and the shift managers previous to the issuance of the new version via training on 1 August 2019, of which records are available.
- With the modification of the HACCP program, control of visible surface contamination of the carcasses became a CCP with effect from 8 August, 2019. An employee was assigned with the task of detecting and removing of such smaller contaminations that can be safely remedied on-line, taking into account the line speed in particular. This employee informs the person who operates the panel on the issue (an electronic registration panel is in operation in this specific establishment for the registration of contaminated carcasses). The panel operator is the official auxiliary in this particular establishment, due to the technology applied. In the case of major contamination that can't be corrected on-line, the abovementioned employee informs the panel operator on the contamination, who then direct the contaminated carcass to the separation line. The panel registers the carcasses corrected on-line and the carcasses sent to the separation line under a different code.
- A randomized check is performed by the shift manager prior to blast chilling, while the carcass is still in the slaughter room, every hour. During this check, 10 randomly selected carcasses are being further inspected for contamination and the inspection is being documented on-site. Should this additional inspection identify contamination on the carcasses, the responsible worker inspects all carcasses slaughtered since the last inspection. The quality manager conducted training on the changes in the program and on the new inspection procedures on 7th August, 2019, which is duly documented.
- Sings indicating the designated areas for U.S. products throughout the establishment will only be deployed when U.S. production takes place, training was conducted accordingly.
- Derusting of the conveyor chain forwarding the carcasses out of the carcass chiller was performed. Derusting of surfaces was incorporated into the Maintenance plan.
- Sorting and removal of damaged, cracked bins (crates) from production is now regulated. Bins are being sorted in the bin washing area, training was conducted accordingly on 1st. August, 2019.
- On 6th August 2019, a comprehensive hygienic training was performed, with an emphasis on the using and storing of the various utensils – e.g. the circular knife near the flooring.
- A total of 4 knives were available in the tool disinfecting unit for the worker who removes the sticking point from the carcasses. The worker was routinely performing the removal of the sticking point with a clean knife on each individual carcass. Training was performed for the workers performing this process step, on 6th August, 2019.

- Training was performed for the workers in the cutting area on 6th August, 2019. Main point of the training was to ensure that occasionally contaminated meat cuts are separated and put into separate containers and will not end up in the bins containing actual product. During the inspection, no contaminated meat was found in the containers designated for actual products.