United States Department of Agriculture

Food Safety and
Inspection Service

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

November 22, 2024

Dr. Borbala Bende
Ministry of Agriculture
Office of the Chief Veterinary Officer
Apáczai Csere János utca 9.
Budapest, Hungary

Dear Dr. Bende,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Hungary's inspection system February 26–March 14, 2024. Enclosed is a copy of the final audit report. The comments received from the Government of Hungary are included as an attachment to the report.

Sincerely,

MARGARET BURNS RATH
Digitally signed by MARGARET BURNS RATH
Date: 2024.11.22 15:27:56 -05'00'

Margaret Burns Rath, JD, MPH
Assistant Administrator
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

HUNGARY

FEBRUARY 26–MARCH 18, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW AND PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 18, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Hungary conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) February 26–March 18, 2024. The purpose of the audit was to verify whether Hungary's food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Hungary is eligible to export pork products under the following process categories to the United States: Raw – Intact, Raw – Non Intact, Not Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, and Heat Treated-Not Fully Cooked-Not Shelf Stable.

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 auditor identified the following findings:

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

- Hungary's Central Competent Authority— National Food Chain Safety Office (NFCSO)— did not ensure proper documentation of competency for new analysts to perform analytical methods independently at the Microbiological National Reference Laboratory (MNRL).
- NFCSO did not ensure that official laboratories properly implement quality control standards consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. Specifically:
  - Samples were not processed within the required time frame, sample receipt procedures were not consistently performed, and sample receipt time for determining compliance with required sample processing time frames was not properly documented at MNRL.
  - The use of positive assay controls throughout the analysis of official samples at MNRL was not properly documented.
  - The Toxicological National Reference Laboratory (TNRL) did not establish calibration frequencies for reference thermometers or properly document verification of performance for working thermometers.
  - TNRL did not implement procedures to ensure reagents, solutions, and consumable supplies used past the expiration date are fit for purpose and do not adversely affect sample results.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- Government inspection personnel assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set

forth in the Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

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.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Hungary's food safety system February 26–March 18, 2024. The audit began with an entrance meeting on February 26, 2024, in Budapest, Hungary, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority –the National Food Chain Safety Office (NFCSO). During the audit exit meeting on March 18, 2024, NFCSO committed to address the preliminary findings. Representatives from NFCSO accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. 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	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible

USDA's Animal and Plant Health Inspection Service (APHIS) subjects pork imported from Hungary to African swine fever (ASF) requirements specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Hungary's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Hungary's food safety inspection system governing raw and processed pork products is being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from NFCSO through the 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.

The FSIS auditor reviewed administrative functions at NFCSO headquarters, one county government office (CGO), one district government office (DGO) and six local inspection offices within the establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

All six establishments certified to export to the United States were included in the audit. This included three pork slaughter and processing establishments, two pork processing establishments, and one cold storage facility. These establishments produce and are eligible to export to the United States raw intact pork, raw non-intact pork, RTE acidified/fermented pork (without cooking), RTE dried pork, RTE fully cooked pork, RTE fully-cooked pork without subsequent exposure to the environment, and NRTE otherwise processed pork products.

During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor 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.

The FSIS auditor also visited one government laboratory conducting microbiological testing and one government laboratory conducting chemical residue testing to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• NFCSO headquarters, Budapest
	County	1	• Baranya CGO, Pécs
	District	1	• Mohács DGO, Mohács
Laboratories		2	• NFCSO Microbiological National Reference Laboratory (government) (microbiological), Budapest • NFCSO Toxicological National Reference Laboratory (government) (chemical residue), Budapest
Pork slaughter and processing establishments		3	• Establishment No. 23, Hungary-Meat Kft., Kiskunfélegyháza • Establishment No. 1360, MCS Vágóhíd Zrt., Mohács • Establishment No.6, Pápai Hús Kft., Pápa
Pork processing establishments		2	• Establishment No. 7, Pick Szeged Zrt. Szeged • Establishment No. 86, Pick Szeged Zrt., Alsómocsolád
Cold storage facility		1	• Establishment No. 553, MCS Vágóhíd Zrt. Pécsi Hűtőháza, Pécs

FSIS performed the audit to verify that the food safety inspection system meets 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.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); 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 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.

III. BACKGROUND

From October 1, 2020, to September 30, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 47,160,137 pounds of raw and processed pork products from Hungary. This included 7,056 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 1,017,549 pounds of RTE fully-cooked pork; 215,541 pounds of RTE dried pork; 169,224 pounds of RTE acidified/fermented pork (without cooking); 45,014,870 pounds of raw intact pork; and 735,897 pounds of NRTE otherwise processed pork exported by Hungary to the United States. Of these amounts, additional types of inspection were performed on 3,877,945 pounds of pork products (190,183 pounds of RTE fully-cooked pork;

47,690 pounds of RTE dried pork; 33,677 pounds of RTE acidified/fermented pork (without cooking); 3,507,059 pounds of raw intact pork; and 99,336 pounds of NRTE otherwise processed pork). These additional types of inspection included physical examination, chemical residue analysis, and testing for microbiological pathogens (i.e., *Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of these additional types of inspection, 63,156 pounds of pork products were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

The previous FSIS audit in 2022 did not identify any systemic findings.

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

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

The first equivalence component the FSIS auditor 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.

Since the previous FSIS audit in 2022, there have been changes to the competent authority for food safety in Hungary. Hungary's Government Decree 182/2022 (v. 24) describes the redistribution of competencies across ministries. The Ministry of Agriculture (MoA) is responsible for managing NFCSO. The Ministry of Public Administration and Regional Development is responsible for managing CGOs and DGOs. The MoA Department of Food Chain Control develops policies, procedures, and guidelines governing the food safety inspection system. The Ministry of Public Administration and Regional Development coordinates the implementation and enforcement of the food safety inspection system requirements. In September 2022, NFCSO established the Directorate for General Control. This subdepartment is responsible for providing regulatory oversight to the establishments certified to export raw and processed pork products to the United States. CGOs and DGOs are independently managed with oversight by NFCSO. Currently, four CGOs and six DGOs oversee establishments that are certified to export to the United States. Government inspection personnel are employees of DGOs.

NFCSO requires establishments to develop written traceability and recall programs in accordance with Act XLVI of 2008 on the Food Chain and Official Controls (hereinafter Act XLVI of 2008). Establishments are required to immediately notify NFCSO as soon as they become aware that adulterated products have been produced and are no longer under their control. NFCSO would immediately notify FSIS if they become aware that adulterated product had been shipped to the United States. The FSIS auditor verified the audited, certified establishments maintain written traceability and recall procedures. The FSIS auditor verified there have not been any recent elevated enforcement measures or recalls in certified

establishments involving raw or processed pork products intended for export to the United States.

NFCSO's export certification process is designed to ensure that raw or processed pork products intended for export to the United States are not adulterated or misbranded and that only eligible pork products are certified for export to the United States. Export certificates must be issued in accordance with Hungary's Ministry of Agriculture and Rural Development Decree 128/2004 (VIII. 19) and NFCSO's Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States (hereinafter Export Procedures). Only official veterinarians who have received training on requirements of Export Procedures can certify exports to the United States. Prior to issuing an export certificate, the official veterinarian reviews and confirms acceptable test results from all microbiological samples, verifies the establishment conducted a pre-shipment review, and performs physical inspection of each consignment. Carcasses and parts sampled for chemical residues are ineligible for export to the United States. Physical inspection of each shipment includes verifying the packing list accurately reflects contents of consignment, accuracy of labels, condition of packages, and condition of the shipping container. The FSIS auditor reviewed noncompliant results from the establishment's microbiological testing of RTE products and verified the DGO was notified, and the affected lot was deemed ineligible for export to the United States. The export certificates have unique identification numbers in series that include the year of issuance. A logbook is maintained containing information on all issued export certificates. The FSIS auditor verified the official veterinarian maintains the export logbook to ensure traceability of export certificates and ensures control of export stamps. The FSIS auditor reviewed export certificates, pre-shipment reviews, and microbiological test results and verified that government inspection personnel were performing export certification procedures as required.

Raw materials transported from a producing facility in Hungary to a processing or dispatching facility in Hungary must be accompanied by a pre-export certificate signed by an official veterinarian. Raw materials transported from a producing facility outside of Hungary to a processing facility in Hungary must be accompanied by an export certificate indicating eligibility for export to the United States. The certifying official veterinarian reviews all associated pre-export certificates and export certificates to verify source materials are from certified establishments eligible to export to the United States. The FSIS auditor reviewed some certificates for products exported to the United States and verified raw materials were documented by either pre-export certificates or export certificates from certified establishments.

Export Procedures describes the procedures an establishment needs to follow to obtain approval from NFCSO to become certified to export raw or processed pork products to the United States. The DGO and CGO conduct a joint onsite inspection at establishments interested in exporting to the United States, and a report is submitted to NFCSO. The Directorate for General Control will then conduct an onsite inspection to determine the establishment's eligibility for export to the United States. Establishments must also sign an attestation stating their intent to comply with FSIS import requirements. A training program organized by the Directorate for General Control in March 2023 included requirements for applying for an exporting license for the United States. There have not been any additional establishments approved for export to the United States since the previous FSIS audit in 2022.

Information regarding U.S. requirements are disseminated in a newsletter from NFCSO to CGOs and from CGOs to DGOs, including government inspection personnel. The FSIS auditor verified that NFCSO's 2024 microbiological sampling plan for establishments certified for export to the United States was distributed via email from NFCSO to the CGO and from the CGO to DGOs.

The CGO is responsible for hiring government inspection personnel and paying their salaries. Government inspection personnel consist of veterinarians, food engineers, and veterinary assistants. The food engineers perform verification tasks in deboning, processing, and cold storage. Veterinary assistants perform post-mortem inspection, sample collection, and other verification tasks under the supervision of the veterinarian. The FSIS auditor reviewed earnings statements from an official veterinarian and a veterinary assistant and verified they are receiving payment from the CGO. Veterinarians and food engineers are civil servants and veterinary assistants are governed by the labor code. Civil servants are required to take conflict-of-interest training and sign a conflict-of-interest declaration. The FSIS auditor reviewed signed conflict-of-interest statements from two government officials.

The Head of the Food Chain Safety and Animal Health Unit at the DGO is responsible for staffing of government inspection personnel, including procedures for coverage during planned and unplanned absences. Establishments must notify the official veterinarian by Friday of the preceding week of planned production for export to the United States. The FSIS auditor reviewed emails from establishments notifying the official veterinarian of planned production for export to the United States and verified the establishments were submitting the request within the required timeframe. The FSIS auditor reviewed staffing records from the establishments certified for export to the United States and verified there was sufficient government inspection personnel scheduled to ensure continuous coverage during slaughter operations and at least once per shift during processing operations when producing products for export to the United States.

Official veterinarians are required to have a veterinary degree, food engineers are required to have a bachelor's degree in food engineering, and veterinary assistants are required to have at least a high school diploma. NFCSO's Training Regime and Procedures for Official Inspection Personnel Overseeing United States Eligible Certified Establishments details requirements for initial and ongoing training for supervisors assigned to establishments eligible for export to the United States. New supervisors must receive a passing score on the exam at the end of training to supervise independently. The Directorate for General Control organizes ongoing training for supervisory personnel every 2 years. The FSIS auditor reviewed documentation of training that occurred in 2023 that included training for *Listeria* and *Salmonella* sampling and verification of control of *Lm* in the RTE processing environment. The CGO also organizes training for CGO and DGO personnel. The FSIS auditor reviewed documentation of training organized by the audited CGO. The training in 2023 included monitoring samples and food production. The training in 2022 included documentation of inspection activities and access to training materials. Newly hired veterinary assistants are trained by the Food Chain Safety and Animal Health Unit of the DGO and they are provided with a CD containing training materials. The newly hired veterinary assistants also receive on-the-job training and at the completion of their training, must pass a written test. Ongoing training of the veterinary assistants is provided by the veterinarians. The FSIS auditor verified that government inspection personnel possess the appropriate

educational credentials, training, and experience to carry out the assigned food safety inspection verification tasks.

NFCSO's Food Chain Safety Laboratory Directorate has the legal authority and responsibility to designate laboratories for conducting analytical testing of products intended for export to the United States in accordance with Act XLVI of 2008. The Microbiological National Reference Laboratory (MNRL) and its satellite laboratories and the Toxicological National Reference Laboratory (TNRL) are the only laboratories designated to perform official microbiological analyses and chemical residue testing for establishments producing product intended for export to the United States. The national reference laboratories are accredited consistent with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards by the Hungarian National Accreditation Authority (NAH). Accreditation is valid for 5 years. MNRL and its satellite laboratories are under one accreditation certificate. The FSIS auditor reviewed the accreditation certificates from MNRL and TNRL and verified the certificates are current. NAH carries out three audits per 5-year accreditation period. NAH audits TNRL and MNRL and each of the satellite laboratories at least once over the 5-year accreditation period. An official from NFCSO's Food Chain Safety Laboratory Directorate attends every audit of the national reference laboratories conducted by NAH. The Food Chain Safety Laboratory Directorate conducts annual supervisory documentary reviews of the national reference laboratories according to ISO/IEC 17025 standards, but not of each satellite laboratory. In addition to NAH audits and the Food Chain Safety Laboratory Directorate supervisory documentary reviews, the laboratory also conducts its own annual internal audits. The FSIS auditor reviewed reports from NAH audits, the Food Chain Safety Laboratory Directorate documentary reviews, and the internal audits and verified the audits were performed at the required frequency and that the laboratories properly responded to address audit findings.

The primary MNRL location is the only laboratory conducting *Lm* testing of RTE products and of environmental samples. The laboratory implements FSIS' Microbiology Laboratory Guidebook (MLG) Chapter 8 method for detection of *Lm*. MNRL's primary location and its satellite laboratories implement testing for *Salmonella* using the ISO 6579 method. The EU requires national reference laboratories to participate in European Union Reference Laboratory (EURL) proficiency tests. NAH requires laboratories to participate in proficiency tests for each of the accredited methods once over the 5-year accreditation period. NAH accepts comparison testing in lieu of proficiency testing. MNRL is required to participate in the EURL-organized proficiency tests, but satellite laboratories are not. The Act XLVI of 2008 requires national reference laboratories to organize proficiency tests for regional laboratories. The satellite laboratories only participate in proficiency tests organized by MNRL. MNRL organized proficiency tests for the ISO 6579 method (for detection of *Salmonella*) for its satellite laboratories in 2022. The satellite laboratories all had acceptable results. MNRL analysts participated in EURL-organized proficiency tests for the ISO 6579 method in 2022 with acceptable results. The analysts at MNRL participate in in-house comparison tests for *Lm* using the MLG Chapter 8 method in lieu of proficiency tests. TNRL participates in EURL-organized proficiency tests for each method once every 5 years. The FSIS auditor reviewed proficiency tests with unacceptable results since the previous FSIS audit in 2022 and verified that the laboratory investigated the causes of the unacceptable results and took corrective actions.

During the visits to the laboratories, the FSIS auditor reviewed records for sample receipt and registration, calibration of equipment, analyst worksheets, supervisory checks on analyst performance, analyst training, sample rejection, and reporting of results.

The FSIS auditor reviewed laboratory personnel training documentation to determine if laboratory personnel are properly trained and proficient in the chemical residue and microbiological analyses being performed. New analysts at MNRL are trained in-house by supervisors on analytical methods. After three months of working under supervision, the new analysts are observed for competency before being able to perform analytical methods independently, but records did not include the date analysts were deemed competent. The FSIS auditor identified the following finding:

- NFCSO did not ensure proper documentation of competency for new analysts to perform analytical methods independently at MNRL.

NFCSO's Procedural Order for Laboratory Testing Included in the Inspection Plan for Microbiological Monitoring states that processing of microbiological samples should begin within 48 hours of sample collection and states the temperature of the sample is to be recorded upon arrival at the laboratory and the sample should be refused if the temperature deviates from the prescribed acceptance criteria. The FSIS auditor visited the sample receipt department at MNRL and reviewed sample receipt documentation. The laboratory employee recorded the date of sample receipt but did not record the time which does not allow for accurate determination of compliance with the required time frame from sample collection to sample processing. The FSIS auditor also reviewed sample receipt documentation that clearly exceeded the required time frame from sample collection to sample processing and the samples were not rejected. The FSIS auditor reviewed multiple sample receipt documents where the temperature of the sample was not recorded at arrival and the sample was processed without verifying compliance with the temperature acceptance criteria.

The FSIS auditor reviewed internal quality control parameters, including positive and negative assay controls where appropriate, to ensure the quality of the results for the analyses performed. The FSIS auditor observed multiple sample worksheets at MNRL that were missing information about positive assay controls used during the analyses. The laboratory manager stated that positive assay controls are always used, but sometimes the analysts fail to document the information.

The FSIS auditor reviewed the quality control procedures and documentation at the MNRL and TNRL to verify that laboratory equipment is being maintained, calibrated and performance monitored at the frequency defined in the quality control procedures. The calibration program at the TNRL states that reference thermometers will be calibrated at the frequency determined by the laboratory. The laboratory manager stated the frequency is as needed or when there is a noticeable issue. The laboratory manager stated that working thermometers are verified against the reference thermometers, but this information is not documented.

During the walkthrough of MNRL and TNRL the FSIS auditor observed reagents, reference materials, and supplies used for analyses to verify proper labeling, including verification of

expiration dates. The FSIS auditor observed expired standards and reagents throughout the TNRL that are routinely used for official chemical residue testing. The laboratory had a procedure to verify the stability of standards when used past the expiration date; however, the laboratory did not have procedures to ensure expired reagents, solutions and consumable supplies were fit for purpose beyond the expiration date.

- NFCSO did not ensure that official laboratories properly implement quality control standards consistent with ISO/IEC 17025. Specifically:
  - Samples were not processed within the required time frame, sample receipt procedures were not consistently performed, and sample receipt time for determining compliance with required sample processing time frames was not properly documented at MNRL.
  - The use of positive assay controls throughout the analysis of official samples at MNRL was not properly documented.
  - TNRL did not establish calibration frequencies for reference thermometers or properly document verification of performance for working thermometers.
  - TNRL did not implement procedures to ensure reagents, solutions and consumable supplies used past the expiration date are fit for purpose and do not adversely affect sample results.

NFCSO requires laboratories to provide results from microbiological analyses within 15 days and results from chemical residue testing within 30 days. Beginning in 2024, all results from official microbiological sampling and noncompliant results from chemical residue testing are provided electronically to the Directorate for General Control, CGO, DGO, and sample collector. Compliant results from chemical residue testing are provided to the CGO and the sample collector. The FSIS auditor verified official government test results are distributed in a timely manner to the required distribution list.

FSIS onsite audit verification activities indicate that NFCSO's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component, except for the laboratory findings detailed above.

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 equivalence component the FSIS auditor 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 every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once-per-shift inspection during processing operations; and periodic supervisory visits to official establishments.

Hungary's Ministry of Rural Development Decree 140/2012 provides requirements for animal welfare and humane handling during transport and slaughter. Official veterinarians are responsible for verification of humane handling daily when animals are unloaded from the trucks and when the animals are in the pens at each certified slaughter establishment. The official

veterinarians perform ad hoc verification of humane slaughter. These routine verification tasks are only documented when noncompliance is observed. Non-ambulatory and injured animals undergo emergency slaughter on the truck or in the pens to ease suffering, and these animals are excluded from export to the United States. The FSIS auditor reviewed documentation of animals that underwent emergency slaughter and verified products from those animals were ineligible for export to the United States. The FSIS auditor verified through interviews and records review that official veterinarians conduct humane handling and slaughter verification activities as required by NFCSO.

Official veterinarians assigned to each certified slaughter establishment perform ante-mortem inspection on every animal prior to slaughter and the inspection includes checks on documentation and health certificates that accompany the livestock, examination of animal identification, assessment of animal cleanliness, and examination of the livestock to determine whether they are fit for slaughter for human food. The animals arrive with a health certificate from the farm of origin certifying the health of the animals and their fitness for transportation. Suspect animals identified during ante-mortem inspection are segregated and the official veterinarian performs a clinical examination. The FSIS auditor verified through interviews and records review that official veterinarians conduct ante-mortem inspection for every lot of animals as required by NFCSO.

Veterinary assistants perform post-mortem inspection of all carcasses and parts according to instructions detailed in Export Procedures. Government inspection personnel are present during all slaughter operations. Post-mortem inspection procedures of carcasses for export to the United States require visual inspection, palpation, and incision. Post-mortem inspection also includes head inspection with mandibular lymph node incision, viscera inspection, and carcass inspection. The FSIS auditor verified through direct observation that veterinary assistants were performing post-mortem inspection as required by NFCSO. Export Procedures states that NFCSO will comply with requirements consistent with 9 CFR 310.1 for the minimum number of veterinary assistants performing post-mortem inspection during slaughter operations. The FSIS auditor verified that the slaughter establishments utilized the number of veterinary assistants required for the number of animals slaughtered per hour. The online veterinary assistants are also responsible for identifying carcasses with fecal, ingesta, or milk contamination. Contaminated carcasses are sent offline for reprocessing. The FSIS auditor observed the online government inspectors requesting contaminated carcasses to be marked and railed out for reprocessing.

Export Procedures require the Directorate for General Control to perform supervisory reviews at the establishments eligible for export to the United States twice per year. Representatives from the CGO and DGO accompany the Directorate for General Control during the supervisory visits. The results of these supervisory reviews are documented on the Central Authority Checklist for Biannual Onsite Inspections of Facilities Approved for United States Export. The FSIS auditor reviewed reports from supervisory reviews conducted by the Directorate for General Control during 2023 and verified they were performed at the required frequency, and that verification of animal welfare, ante-mortem, post-mortem, sanitation standard operating procedures (Sanitation SOPs) and sanitation performance standards (SPS), HACCP, establishment sampling programs and results, and official government sample procedures were included in the review. The

Directorate for General Control also verifies corrective actions in response to deficiencies identified during previous supervisory reviews.

Export Procedures require the CGO to perform quarterly supervisory reviews at establishments eligible for export to the United States. During the supervisory review, the CGO walks through the entire production process for products for export to the United States. The FSIS auditor reviewed reports from supervisory reviews conducted in 2023 by the audited CGO and verified they were conducted at the required frequency, and that verification of animal welfare, ante-mortem, post-mortem, Sanitation SOPs and SPS, HACCP, establishment sampling programs and results, and official government sample procedures were included in the review.

DGO oversight of establishments varies from district to district. Some DGOs perform monthly oversight activities, and some only accompany the Directorate for General Control and CGOs during biannual and quarterly visits. The audited DGO conducts oversight activities during the Directorate for General Control and CGO's biannual and quarterly visits.

Act XLVI of 2008 requires establishments to have systems in place that ensure traceability and identifiability. Establishments certified to export to the United States must maintain identity of products and control and segregate product intended for export to the United States from other products, as applicable. The FSIS auditor verified at all certified establishments that product eligible for export to the United States was separated from products ineligible for export to the United States either through time, space, or identifying marks.

Establishments have a dedicated production line for U.S.-eligible products and the U.S.-eligible raw materials are stored in a designated cooler. Government inspection personnel perform label verification and visual inspection of raw materials for species verification. In establishments that produce products from multiple species in the same production area, species testing is performed. Currently there are no establishments eligible for export to the United States that produce products from multiple species in the same production area. The FSIS auditor verified that government inspection personnel are performing label verification and visual inspection of incoming raw materials used to produce products eligible for export to the United States.

Export Procedures requires establishments to obtain label approval from the FSIS. The FSIS auditor verified the establishments had label approvals on file from FSIS. The FSIS auditor informed NFCSO that FSIS will no longer review labels for products that are eligible for generic label approval.

NFCSO receives information regarding APHIS restrictions from the APHIS website. Hungary currently has restricted zones I and II established by the EU because of detection of ASF in feral swine. Certain pork products produced from swine sourced from any restricted zone established by the EU are restricted by APHIS from importation into the United States. The FSIS auditor identified animal health certificates accompanying products produced from swine sourced from farms located in a restricted zone that are not eligible for export to the United States. Although this was not a food safety issue, the FSIS auditor was able to determine that the government inspection personnel signed export certificates for APHIS-restricted products produced from swine in European Union established restricted zone I for ASF, as defined in Commission

Implementing Regulation (EU) 2023/594. FSIS has communicated the animal health findings related to the control of ASF to APHIS for further follow-up.

Hungary's Ministry of Rural Development Decree 45/2012 (V.8) contains rules regarding by-products of animal origin not intended for human consumption in accordance with Regulation (EC) No. 1069/2009 and Commission Regulation (EU) No. 142/2011. The FSIS auditor verified through observation and records review that government inspection personnel ensure condemned and inedible materials are controlled and not used to produce human food for export to the United States.

The FSIS auditor verified that NFCSO has the legal authority to establish regulatory controls over meat establishments that are eligible to export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

NFCSO requires certified establishments to implement good hygiene practices in accordance with Regulation (EC) No. 853/2004 that requires slaughter and dressing steps to be carried out without undue delay and in a manner that avoids contaminating the meat. The FSIS auditor verified the slaughter establishments have considered sanitary conditions for steps in the slaughter and dressing process. Government inspection personnel verify the establishment's good hygiene practices in the live animal holding pens and during slaughter and dressing as part of ante-mortem, SPS, and Sanitation SOP verification tasks. The FSIS auditor confirmed through direct observation, interviews, and records review that government inspection personnel perform daily verification tasks to ensure livestock are slaughtered and processed in a sanitary manner.

Regulation (EC) No. 853/2004 requires establishments to implement good hygiene practices to ensure that carcasses do not have visible fecal contamination. An official veterinarian is always present during slaughter operations and performs offline verification of zero tolerance for fecal, ingesta, and milk contamination through observance of online veterinary assistants performing post-mortem inspection and examination of carcasses for visible contamination. The FSIS auditor verified the continuous presence of official veterinarians on the slaughter floor evaluating carcasses sent offline and monitoring of veterinary assistants performing post-mortem inspection and examination for visible contamination.

NFCSO's Official Guide requires establishments to develop procedures to address SPS, including cleaning, facility construction and maintenance, equipment maintenance, and pest control consistent with the FSIS sanitation regulations in 9 CFR part 416. Official SPS verification tasks are performed during quarterly CGO audits and biannual NFCSO audits. Government inspection personnel also verify general sanitation during their daily walkthrough of the establishments producing products for export to the United States. The FSIS auditor also

verified through records review that government inspection personnel are performing SPS verification tasks during the quarterly CGO audits and biannual NFCSO audits.

NFCSO requires establishments certified as eligible for export to the United States to develop and adhere to written programs that prevent direct product contamination. On the days that products are being processed for export to the United States, government inspection personnel perform verification of pre-operational and operational Sanitation SOPs in accordance with Export Procedures. A noncompliance summary is included in the monthly report that is generated by the official veterinarian for the DGO. The FSIS auditor verified that government inspection personnel are performing pre-operational and operational Sanitation SOP verification on days that products are produced for export to the United States. The FSIS auditor observed pre-operational Sanitation SOP verification at one audited slaughter establishment and verified the official veterinarian required the establishment to perform corrective actions prior to releasing the establishment to begin production. The FSIS auditor reviewed reports of noncompliance during pre-operational and operational Sanitation SOP verification and records demonstrating the establishment's corrective actions, as verified by government inspection personnel, were implemented and effective.

FSIS onsite audit verification activities indicate that NFCSO's inspection system for raw and processed pork products maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditor identified isolated noncompliance related to government inspection verification of sanitation requirements. These 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 equivalence component the FSIS auditor reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Export Procedures requires certified establishments to design, implement, and maintain HACCP systems consistent with FSIS HACCP regulations in 9 CFR part 417. The HACCP system must include written hazard analyses, flow charts, and HACCP plans that identify, evaluate, and prevent or control food safety hazards throughout the production process. NFCSO requires establishments' HACCP plans to include activities designed to validate the adequacy of controls, monitoring, and verification procedures; records for documenting results of monitoring and verification activities; and corrective actions in response to deviations from critical limits. The FSIS auditor reviewed documents associated with HACCP systems at every audited establishment. The FSIS auditor observed critical control point (CCP) monitoring by the establishment and reviewed records associated with the establishments' design and implementation of their HACCP systems, including their hazard analyses, flow charts, CCPs, critical limits, monitoring procedures and frequencies, initial validation, ongoing verification, reassessment, records, and pre-shipment review.

Export Procedures requires government inspection personnel to perform a monthly HACCP verification task, including observation of establishment monitoring of CCPs. The result of this verification task is documented in the monthly report for the DGO. Records reviewed by the FSIS auditor at the audited establishments revealed that government inspection personnel did not document issues such as: 1) flow chart did not accurately describe product flow; 2) HACCP plan not including verification of monitoring; 3) CCP monitoring records not including the time the event occurred; 4) HACCP plan not requiring corrective actions for every deviation from a critical limit; 5) HACCP plans not including calibration of process monitoring devices; 6) HACCP plan not including all corrective action requirements; 7) HACCP plan not including corrective actions for deviations from the critical limit identified during monitoring; 8) monitoring procedures not being performed as described in the HACCP plan; and 9) establishments not maintaining supporting documentation for decisions made in the HACCP plan. Additionally, the FSIS auditor identified that government inspection personnel in one establishment did not perform the HACCP verification task at the frequency required in Export Procedures. As a result of these observations, the FSIS auditor identified the following finding:

- Government inspection personnel assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set forth in the Export Procedures regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

FSIS onsite audit verification activities indicate that NFCSO requires establishments to develop, implement, and maintain a HACCP system that is consistent with criteria established for this component; however, NFCSO is not ensuring that government inspection personnel verify the HACCP systems fully comply with their requirements as noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Hungary's National Residue Monitoring Plan (NRMP) is issued annually by NFCSO pursuant to specific provisions related to the monitoring of chemical residues found in Commission Delegated Regulation (EU) 2022/1644, Commission Implementing Regulation (EU) 2022/1646, and Hungary's Ministry of Agriculture and Rural Development Decree 10/2002 (I.23). The NRMP is developed in collaboration with TNRL. The design of the NRMP ensures that the plan covers all aspects of food safety in foods derived from animal origin. This includes animal species, veterinary drugs, pesticides, environmental contaminants, methods of analyses, stage of production, and processing and distribution where the samples must be taken. The number of proposed samples is based on the previous year's slaughter and production volumes and the

frequency of violations. Once the NRMP is finalized, it is sent to the Food and Feed Safety Directorate to be distributed to the CGO. CGOs correlate with DGOs to select the sampling sites based on the number of slaughter establishments and the volume of animals slaughtered within the DGO's jurisdiction. Official veterinarians also have the option to collect samples when animals offered for slaughter are suspected of illegal treatment with veterinary drugs, clinical symptoms, or noncompliance with the withdrawal period for veterinary drugs.

Samples collected by the official veterinarian must be packaged and shipped in a manner that ensures the sample is not damaged or compromised and ensures the sample's identity and integrity. The CGO verifies execution of the NRMP during the quarterly audits. The CGO also coordinates corrective actions in response to violative chemical residue sample results and requests the DGO to investigate the cause of violative results and submit a report of their investigative findings. The CGO will then submit a summary report to NFCSO. The FSIS auditor reviewed the 2024 monthly schedules for the NRMP and verified the official veterinarians had collected the samples according to the schedule. The FSIS auditor verified that official veterinarians also identify suspect animals warranting chemical residue testing when necessary.

The FSIS onsite audit and verification activities indicate that NFCSO continues to maintain overall authority for a chemical residue testing program, which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in meat products intended for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2022.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat prepared for export to the United States is safe and wholesome.

Hungary's Export Procedures require that all slaughter establishments certified to export to the United States implement an indicator organism testing program for two points in the slaughter and dressing process (i.e., pre-evisceration and post-chill) to monitor the effectiveness of the process for control of enteric pathogens. During the audit of the slaughter establishments and records review, the FSIS auditor confirmed that carcass samples are collected and analyzed for indicator organisms at pre-evisceration and post-chill locations. The pre-evisceration results are compared to the post-chill results to verify process control. Results are considered satisfactory if the levels do not increase significantly during the slaughter and dressing process. The post-chill results are evaluated based on the most recent 13 results, and establishments must take action if they fail to meet the criteria set in Export Procedures. The CGO and Directorate for General Control verify the indicator organism testing procedures and records during quarterly and biannual audits. The FSIS auditor's assessment of the microbiological sampling and testing program for indicators of intestinal and fecal contamination did not raise any concerns.

NFCSO continues to implement an official government sampling verification program for swine carcasses to verify control of *Salmonella*. The requirements regarding sampling frequency, carcass sampling sites, sample collection method, submission of samples to the designated laboratory, laboratory testing methods, criteria for evaluation of results, and enforcement strategies when criteria are not met are described in Export Requirements. The CGO and Directorate for General Control verify official *Salmonella* carcass sampling procedures during quarterly and biannual audits. The FSIS auditor reviewed government inspection personnel verification activities through document review, interviews, and site visits at the slaughter establishments eligible for export to the United States. The FSIS auditor's review of official inspection records, including certificates of test analysis, indicated that the process control sampling programs for *Salmonella* carcass sampling are being implemented as required by NFCSO.

Export Procedures sets a zero-tolerance requirement for *Lm* and *Salmonella* in RTE pork products and for RTE pork products that come into direct contact with food contact surfaces (FCS) contaminated with *Lm*. The requirements in Export Procedures are consistent with FSIS regulations on *Listeria* control in 9 CFR part 430. An official verification sampling program for *Salmonella* and *Lm* in RTE products and *Lm* on FCS and environmental surfaces is administered annually for establishments certified to export products to the United States. The FSIS auditor verified the official veterinarians were collecting the samples in accordance with NFCSO's 2024 official verification sampling program and the results reviewed were acceptable.

The FSIS auditor noted that RTE establishments producing post-lethality exposed (PLE) products are controlling hazards of *Listeria* contamination by adopting measures consistent with one of the three alternatives in FSIS regulation 9 CFR part 430. The establishment's self-control measures include microbiological testing of product and of FCS and non-food contact surfaces (NFCS). The scope and range of frequencies of the testing regimen are poised with alternatives chosen by establishments producing PLE-RTE products to control *Listeria* contamination in the products. The FSIS auditor reviewed the testing programs at each certified RTE establishment and confirmed that the testing plan and testing frequencies conform to the requirements laid down in the Export Procedures. The FSIS auditor verified that establishments are submitting samples to MNRL for *Lm* testing using the FSIS MLG Chapter 8 method. The MNRL laboratory network analyzes RTE product samples for *Salmonella* using the ISO 6579 method. Batches of product intended for export to the United States are held until pending receipt of acceptable results from official or establishment testing. The FSIS auditor verified that RTE products with *Lm*-positive results and RTE products associated with *Lm*-positive FCS were deemed ineligible for export to the United States. The FSIS auditor also verified the establishment determines the root cause, takes corrective actions, and performs additional cleaning and repeat sampling to prove the effectiveness of the corrective actions when a FCS tests positive for *Lm*.

The establishment producing dried or fermented products implemented processes and CCPs that are validated and support control of spore-forming bacteria. Both establishments producing RTE shelf-stable products set lethality targets of at least a 5.0-log reduction of *Salmonella* and at least a 3.0-log reduction in *Lm*. Both establishments test finished products for *Staphylococcus aureus* once a year. NFCSO's 2024 sampling program for certified establishments exporting not heat treated shelf-stable RTE products to the United States requires 10 official samples per year for

chemical parameters such as salt content, pH, nitrites, and nitrates that contribute to the prevention of growth of spore formers. The FSIS auditor verified the validation documentation supports the lethality targets established. The FSIS auditor verified the establishment tests finished products for *Staphylococcus aureus* once a year and the government inspection personnel are sampling finished products for chemical parameters at the frequency required by NFCSO.

The FSIS auditor determined that NFCSO maintains the overall authority to implement its microbiological sampling and testing programs to ensure that raw and processed pork products for export to the United States are unadulterated, safe, and wholesome. The FSIS auditor identified an isolated noncompliance related to government microbiological testing programs. This is noted in the individual establishment checklist provided in Appendix A of this report. There have not been any POE violations related to this component since the previous FSIS audit in 2022.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 18, 2024, in Budapest, Hungary, with NFCSO. At this meeting, the FSIS auditor 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 auditor identified the following findings:

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

- NFCSO did not ensure proper documentation of competency for new analysts to perform analytical methods independently at the MNRL.
- NFCSO did not ensure that official laboratories properly implement quality control standards consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. Specifically:
  - Samples were not processed within the required time frame, sample receipt procedures were not consistently performed, and sample receipt time for determining compliance with required sample processing time frames was not properly documented at MNRL.
  - The use of positive assay controls throughout the analysis of official samples at MNRL was not properly documented.
  - TNRL did not establish calibration frequencies for reference thermometers or properly document verification of performance for working thermometers.
  - TNRL did not implement procedures to ensure reagents, solutions and consumable supplies used past the expiration date are fit for purpose and do not adversely affect sample results.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- Government inspection personnel assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set forth in the Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States regarding the design of the hazard analysis and HACCP plan, implementation

of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

During the audit exit meeting, NFCSO committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the 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. Kisfaludy u. 2. 8500 Papa	03/08/2024	6	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Fully cooked not shelf stable ham and heat treated but not fully cooked-not shelf stable slab bacon

60. Observation of the Establishment

16. HACCP plan does not include the record where corrective actions are documented.

18. CCP1B monitoring procedures are not being performed as described in the HACCP plan. The HACCP plan states the product core temperature will be continuously monitored during the cooking cycle by cooker operator; however, the product core temperature is continuously monitored by a computer which produces a graph of the product temperature throughout the cooking cycle. The cooker operator reviews the graph and verifies the product reached the required temperature.

22. Records of verification of CCP1B monitoring does not include the time or result of the verification procedure.

45. During walkthrough of establishment, FSIS auditor observed peeling stickers on equipment handling exposed ground product.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/08/2024

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	03/11/2024	7	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling	X	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	Winter salami

60. Observation of the Establishment

15. The HACCP plan does not include corrective actions for CCP1 to identify and eliminate the cause of the deviation, to bring the CCP back under control, and to prevent recurrence. The establishment has an SOP that requires an investigation into the cause of the deviation, but this information is not included in the HACCP plan and is not linked to the documentation of the CCP1 deviation on the monitoring record.

25. Establishment did not maintain detailed information from FSIS LPDS related to required label modifications as required by Hungary's Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/11/2024

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	03/12/2024	23	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork

60. Observation of the Establishment

7. The establishment has a set schedule for performing operational Sanitation SOP monitoring based on even and odd weeks. Hungary's Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America requires the establishment to vary the times for performing operational Sanitation SOP monitoring.

11. During the walk through of the establishment, the FSIS auditor observed grease on a carcass in the cooler and observed flakes of grease hanging from the rail above the carcasses. The FSIS auditor notified the government inspection personnel and the establishment and was informed that contamination is removed from carcasses when they exit the cooler. The establishment's Sanitation SOPs are not preventing product contamination during carcass storage.

15. The HACCP plan does not require corrective actions for every deviation from a critical limit to identify and eliminate the cause, to bring the CCP back under control, and to prevent recurrence.

22. CCP monitoring records do not include the time or initial of the establishment employee making the entry.

41. During the walk through of the establishment, the FSIS auditor observed condensation dripping from an overhead light fixture in the cutting department. There was no product involved.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/12/2024

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	03/06/2024	86	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling	X	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	Mold free salami

60. Observation of the Establishment

14. The establishment does not have information to support their decision for a critical limit of 32 hours for fermented product to reach pH of 5.3.

14. The establishment's hazard analysis does not consider biological hazards associated with outgrowth and toxin production by *Staphylococcus aureus* during fermentation.

15. Establishment's HACCP plans do not include calibration of process monitoring devices.

25. Establishment does not have a label approval on file for products for export to the U.S. as required by the Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/06/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
MCS Vagohid Zrt. tuskesreti ut 40753 hrsz. 7622 Pecs	03/01/2024	553	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	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.	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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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.	

Establishment Operations:	Pork processing and cold storage
Prepared Products:	NA

60. Observation of the Establishment

14. The establishment's flow chart does not accurately describe product flow. Flow chart shows all products going through steps that are specific for pre-cooled hams; however, frozen pork bellies do not go through those steps.

15. Deviations from CCP defined critical limits do not always result in corrective actions because some of the defined critical limits are for sorting. CCP1 is for the temperature of products at receiving. There are 3 sets of critical limits for CCP1: 1) Greater than 4 °C (initiate corrective actions), 2) Between -11 °C and 4 °C (send to blast freezer), and 3) Less than -11.1 °C (send to regular freezer).

15. HACCP plan does not include calibration of process monitoring devices.

15. HACCP plan does not include verification of monitoring. The HACCP plan lists the pre-shipment review as verification of monitoring. The establishment stated that a shift manager observes every monitoring event, but this information is not included in the HACCP plan or documented.

22. CCP monitoring records do not include the time the event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/01/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
MCs Vagohid Zrt. Pick Márk út 1 7700 Mohacs	03/05/2024	1360	Hungary
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork bellies

60. Observation of the Establishment

10. During the observation of pre-operational Sanitation SOP verification by government inspection personnel, FSIS auditor observed a stand and associated equipment in the selected area of the slaughter department that contained blood splatter and debris from previous day's production. The FSIS auditor also observed debris from the previous day's production on other pieces of equipment within the selected area of the slaughter department that was not identified by the government inspection personnel during his pre-operational Sanitation SOP verification. The FSIS auditor notified the government inspection personnel, and he initiated regulatory control of the selected area of the slaughter department until sanitary conditions were restored.

12. The establishment's Sanitation SOP corrective actions records do not identify affected product or the disposition of the affected product.

14. Potential biological hazards are identified for return product in the hazard analysis, but the hazard analysis does not state how the biological hazards are prevented or controlled.

15. Corrective actions are not performed for monitoring deviations for the CCP for zero tolerance of fecal, ingesta, and milk. Corrective actions are inly performed for deviations identified during verification of monitoring.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2024

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

DRAFT FINAL REPORT OF AN AUDIT CONDUCTED OF HUNGARY FEBRUARY 26–MARCH 18, 2024		
Page	Findings	Action proposed by the competent authority
i	National Food Chain Safety Office (NFCSO) did not ensure proper documentation of competency for new analysts to perform analytical methods independently at the Microbiological National Reference Laboratory (MNRL).	The new analyst is allowed to perform the method independently from the date of successful exam on the method. The procedure and the sheet for documentation are attached . (ME-02_Procedure on employee training_2022.09.01.pdf ME-02_Procedure on employee training_2022.09.01_machine translatedEN.docx Microbiological NRL ÜM_08_Employee training_examination_activity control.pdf Microbiological NRL ÜM_08_Employee training_examination_activity control_machine translated EN.docx)
12	Samples were not processed within the required time frame, sample receipt procedures were not consistently performed, and sample receipt time for determining compliance with required sample processing time frames was not properly documented at MNRL.	Samples received after 48 hours are refused with the immediate notification sent to the sampler (Document attached). (Sampling document microbiology 512697.PDF Refusing microbiological samples_ 512697.PDF) Samples for *Salmonella* testing of Mohacs were directed to Microbiological National Reference Laboratory location Kaposvar. The samples can arrive to this laboratory in 24 hours.

		A document was prepared for colleauges working at the sample reception unit summarizing the temperature requirement of all types samples. (Document attached) (Sample reception temperature requirements v3.0_machine translated EN.xlsx) Our colleauge responsible for quality control checks the documentation of sample reception monthly and no mistakes were found after the audit.
12	The use of positive assay controls throughout the analysis of official samples at MNRL was not properly documented.	A staff trainig were organized for the colleauges taking part in sample reception and testing of US export samples. (Document attached) (Staff tranining Microbiological NRL 2024 03 20 signed.pdf Staff tranining Microbiological NRL 2024 03 20 machine translated _EN.docx) We checked the documentation of positive assay controls for 6 months backward. There was one set of samples (positive assay control's result is written to the first sample in the set of samples tested together) where the documentation was missing. We called the attention of colleauges to document the assay controls properly. Our colleauge responsible for quality control checks the USDA testing documentation monthly and no mistakes were found after the audit.
12	TNRL did not establish calibration frequencies for reference thermometers or properly document verification of performance for working thermometers.	During the audit, we presented the documents on site and sent them as attachments after the audit. Please find it attached again. Angol_ÜM_03_példa.pdf Angol_ÜM_03_2_példa.pdf ME-04_Mérőberendezések_kezelése_2019_01_15.pdf, ME-04_MANAGEMENT OF MEASURING EQUIPMENT 2019_01_15_en.pdf, ME-05 Kalibrálás, hitelesítés ellenőrzése 2023.10.02.pdf,

		ME-05. Calibration, Validation, Verification 2023.10.02 en pdf Daily temperature check_ÜM_25.pdf).
11	The laboratory manager stated the frequency is as needed or when there is a noticeable issue. The laboratory manager stated that working thermometers are verified against the reference thermometers, but this information is not documented.	The translation was probably misunderstanding, during the audit we presented the paper-based documentation for both questions, please find it attached. (Angol_ÜM_03_példa.pdf Angol_ÜM_03_2_példa.pdf)
12	TNRL did not implement procedures to ensure reagents, solutions and consumable supplies used past the expiration date are fit for purpose and do not adversely affect sample results.	Please find attached the data sheet in Hungarian and English from the Quality Control Manual, which is the Assurance of Examination Results ME-18. The relevant part is marked in yellow. As well as a calculation example. (ME-18_Az eredmények érvényességének biztosítása _2019_04_17.pdf ME_18 Ensuring the validaty of test results.pdf ENSURING THE VALIDITY OF TEST RESULTS.pdf
17	Government inspection personnel assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set forth in the Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.	The procedures for the export of foodstuffs of animal origin from Hungary to the United States of America document was modified after the audit. The current edition (17.05.2024) provides more details on the responsibilities of the different levels of authorities for the official control of HACCP. The day-to-day implementation of HACCP is checked by the district authority, the county government office reviews the documents kept by the establishment on a quarterly basis and the central authority reviews the adequacy of the content of the HACCP plan and the related official controls.
	Foreign Establishment Audit Checklist Establishment NO. 6 16. HACCP plan does not include the record where corrective actions are documented.	16,18,22: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority.

	18. CCP1B monitoring procedures are not being performed as described in the HACCP plan. The HACCP plan states the product core temperature will be continuously monitored during the cooking cycle by cooker operator; however, the product core temperature is continuously monitored by a computer which produces a graph of the product temperature throughout the cooking cycle. The cooker operator reviews the graph and verifies the product reached the required temperature. 22. Records of verification of CCP1B monitoring does not include the time or result of the verification procedure. 45.(There is an X in Equipment and utensiles, but no detailed description. During exit meeting the following preliminary finding was described: FSIS auditor observed peeling stickers on equipment handling exposed ground product)	45: The sticker was eliminated, see attached InjectStar.jpg
20	The FSIS auditor identified an isolated noncompliance related to government microbiological testing programs. This is noted in the individual establishment checklist provded is Appendix A of this report (There is no detailed discription in Appendix A. During exit meeting the following preliminary audit finding was described: Government official did not follow sterile procedures when performing Salmonella carcass sampling.)	After the audit, training on the proper conduct of official sampling was provided to the persons responsible for official microbiological sampling. The original training report (papahu855.pdf) and its English translation (Training Report-Pápai Hús.docx) are attached.
	Foreign Establishment Audit Checklist Establishment NO. 7 15. The HACCP plan does not include corrective actions for CCP1 to identify and eliminate the cause of the deviation, to bring the CCP back under control, and to prevent recurrence. The establishment has an SOP that requires an investigation into the cause of the deviation, but this information is not included in the HACCP plan and is not linked to the documentation of the CCP1 deviation on the monitoring record.	15: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority. 25: The updated export procedure includes the guidance on label approval. A sample of the currently valid label (not challenged during import control) is available to the local authority. The authority's role in label verification has been detailed in the procedures. The available authorisation document and the valid

	25. Establishment did not maintain detailed information from FSIS LPDS related to required label modifications as required by Hungary's Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America.	labels are attached (Label authorisation.pdf, Label sample Tm.pdf, Label sample Tmidi.pdf, Label sample TN.pdf, Label sample Tt.pdf)
	Foreign Establishment Audit Checklist Establishment NO. 23 7. The establishment has a set schedule for performing operational Sanitation SOP monitoring based on even and odd weeks. Hungary's Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America requires the establishment to vary the times for performing operational Sanitation SOP monitoring. 11. During the walk through of the establishment, the FSIS auditor observed grease on a carcass in the cooler and observed flakes of grease hanging from the rail above the carcasses. The FSIS auditor notified the government inspection personnel and the establishment and was informed that contamination is removed from carcasses when they exit the cooler. The establishment's Sanitation SOPs are not preventing product contamination during carcass storage. 15. The HACCP plan does not require corrective actions for every deviation from a critical limit to identify and eliminate the cause, to bring the CCP back under control, and to prevent recurrence. 22. CCP monitoring records do not include the time or initial of the establishment employee making the entry. 41. During the walk through of the establishment, the FSIS auditor observed condensation dripping from an overhead light fixture in the cutting department. There was no product involved.	7: The SSOP plan has been revised (please find attached the latest valid document - SSOP.pdf). The timeframe for SSOP inspections has been changed (English translation of the relevant part: SSOP manual_v08_part02.pdf) The review of the SSOP plan and the verification of its operation in compliance with the requirements will be carried out during the second biannual inspection by the central authority. 11: The SSOP plan has been revised (please find attached the latest valid document - SSOP.pdf). The protection of the carcasses from grease contamination is part of the plan (English translation of the relevant part :SSOP manual_v08_part01.pdf) The review of the plan and the verification of its operation in compliance with the requirements will be carried out during the second biannual visit of the central authority. 15, 22: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority. 41: The ventilation system has been reviewed. The document on the inspection is attached (Skeleton ventilation system inspection.pdf)
	Foreign Establishment Audit Checklist Establishment NO. 86	

	14. The establishment does not have information to support their decision for a critical limit of 32 hours for fermented product to reach pH of 5.3. 14. The establishment's hazard analysis does not consider biological hazards associated with outgrowth and toxin production by *Staphylococcus aureus* during fermentation. 15. Establishment's HACCP plans do not include calibration of process monitoring devices. 25. Establishment does not have a label approval on file for products for export to the U.S. as required by the Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America.	14,14,15: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority. 25: The updated export procedure includes the guidance on label approval. A sample of the currently valid label (not challenged during import control) is available to the local authority. The authority's role in label verification has been detailed in the procedures. We attach the valid labels (CIMKE_P._BATH_USA_50X80_A1_300g_front_cimke.jpg, 335195_USA_Bathory_300g_termek_cimke.jpg, CIMKE_P._BATH_USA_50X80_A1_600g_front_cimke.jpg, 335194_USA_Bathory_600g_termek_cimke .jpg, CIMKE_P._BATH_USA_50X80_A1_1100g_front_cimke.jpg, 336205_USA_Bathory_1100g_termek_cimke.jpg)
	Foreign Establishment Audit Checklist Establishment NO. 553 14. The establishment's flow chart does not accurately describe product flow. Flow chart shows all products going through steps that are specific for pre-cooled hams; however, frozen pork bellies do not go through those steps. 15. Deviations from CCP defined critical limits do not always result in corrective actions because some of the defined critical limits are for sorting. CCP1 is for the temperature of products at receiving. There are 3 sets of critical limits for CCP1: 1) Greater than 4 °C (initiate corrective actions), 2) Between -11 °C and 4 °C (send to blast freezer), and 3) Less than -11.1 °C (send to regular freezer). 15. HACCP plan does not include calibration of process monitoring devices.	14, 15, 15, 15, 22: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority.

	15. HACCP plan does not include verification of monitoring. The HACCP plan lists the pre-shipment review as verification of monitoring. The establishment stated that a shift manager observes every monitoring event, but this information is not included in the HACCP plan or documented. 22. CCP monitoring records do not include the time the event occurred.	
	Foreign Establishment Audit Checklist Establishment NO. 1360 10. During the observation of pre-operational Sanitation SOP verification by government inspection personnel, FSIS auditor observed a stand and associated equipment in the selected area of the slaughter department that contained blood splatter and debris from previous day's production. The FSIS auditor also observed debris from the previous day's production on other pieces of equipment within the selected area of the slaughter department that was not identified by the government inspection personnel during his pre-operational Sanitation SOP verification. The FSIS auditor notified the government inspection personnel, and he initiated regulatory control of the selected area of the slaughter department until sanitary conditions were restored. 12. The establishment's Sanitation SOP corrective actions records do not identify affected product or the disposition of the affected product. 14. Potential biological hazards are identified for return product in the hazard analysis, but the hazard analysis does not state how the biological hazards are prevented or controlled. 15. Corrective actions are not performed for monitoring deviations for the CCP for zero tolerance of fecal, ingesta, and	10: The Procedures for the export of foodstuffs of animal origin from Hungary to the United States of America document was modified after the audit. The current edition (17.05.2024) provides more details on the preop inspections carried out by the official personnel. 12: The SSOP plan has revised. Attached is a document for a product found to be non-compliant during an SSOP audit, indicating the product and its disposition (Belső problémás termék kezelés_magyar_angol.xls). The plan will be reviewed and verified to ensure that it is operating in compliance with the requirements during the second biannual inspection by the Central Authority. 14,15: The company has modified its HACCP plan. The plan will be revised in detail and compared to the actual implementation during the second biannual inspection by the central authority.

	milk. Corrective actions are inly performed for deviations identified during verification of monitoring.	