



United States Department of Agriculture

DEC 15 2022

Food Safety and
Inspection Service

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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 Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Hungary's meat inspection system from June 7 through July 21, 2022. 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,

A handwritten signature in blue ink, appearing to read "Michelle Catlin", is positioned above the typed name.

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
HUNGARY

JUNE 7 TO JULY 21, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

December 13, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Hungary conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from June 7 to July 21, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to verify whether Hungary's food safety inspection system governing 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 currently exports raw intact and raw non-intact pork products, as well as not heat treated-shelf stable, fully cooked-not shelf stable and heat treated-not fully cooked-not shelf stable pork products to the United States.

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

FSIS concluded that Hungary's pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The National Food Chain Safety Office (NFCSO), the Central Competent Authority (CCA) for Hungary, has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, the CCA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Hungary's food safety system from June 7 to July 21, 2022. The audit began with an entrance meeting held via videoconference on June 7, with the Central Competent Authority (CCA) - the National Food Chain Safety Office (NFCSO). Representatives from NFCSO participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Hungary is eligible to export 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

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Hungary as subject to the following restrictions: African swine fever requirements specified in Title 9 of the United States 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 pork used to produce products must originate from eligible countries and establishments certified to export to the United States.

Prior to the remote 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 and reviewed records to determine whether Hungary's food safety inspection system governing 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 records related to administrative functions and oversight at NFCSO headquarters, as well as government verification records from two county offices, and three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over a 7-week period. Through records review, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

A sample of three establishments was selected for the remote audit from a total of six establishments certified to export to the United States. This included two pork slaughter and processing establishments, and one pork processing establishment. The products these establishments produce and export to the United States include raw intact and raw non-intact pork, as well as not heat treated-shelf stable, fully cooked-not shelf stable and heat treated-not fully cooked-not shelf stable pork.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of onsite establishments' conditions or records. The FSIS auditor assessed the CCA'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 remotely audited one official microbiological laboratory and one official chemical residue laboratory to verify that the laboratory system is capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> NFC SO, Budapest
	County Offices	2	<ul style="list-style-type: none"> Bács-Kiskun County Government Office (CGO), Bács-Kiskun Baranya County Government Office, Baranya
Laboratories		2	<ul style="list-style-type: none"> NFC SO National Reference Laboratory for Microbiology, Budapest NFC SO National Reference Laboratory for Residues, Budapest
Pork slaughter and processing establishments		2	<ul style="list-style-type: none"> Establishment No. HU 23 EK, Hungary Meat Kft., Kiskunfélegyháza Establishment No. HU 1360 EK, MCs Vágóhíd Zrt., Mohács
Pork processing establishment		1	<ul style="list-style-type: none"> Establishment No. HU 86 EK, Pick Szeged Zrt., Alsómocsoládi Gyáregysége, Alsómocsoládi

FSIS performed the audit to verify that Hungary's 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 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Hungary's inspection system for 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 February 1, 2019, to January 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 33,945,337 pounds of pork products. These products imported into the United States included 31,817,058 pounds of raw intact pork, 749,872 pounds of NRTE otherwise processed pork, 152,711 pounds of RTE dried pork, 875,376 pounds of RTE fully cooked pork, 321,664 pounds of RTE acidified/fermented pork (without cooking), and 28,656 pounds of RTE meat fully-cooked without subsequent exposure to the environment exported by Hungary to the United States.

Of this volume, FSIS also performed reinspection on 3,501,272 pounds at POE for additional types of inspection, including physical examination, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* (*Lm*) and *Salmonella* in ready-to-eat (RTE) products). As a result of this additional testing no pork products were rejected.

The previous FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Hungary	
Component 1: Government Oversight (e.g., Organization and Administration)	
<ul style="list-style-type: none"> The NFCSO inspection personnel were not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing and stamping of the export certificate. 	
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)	
<ul style="list-style-type: none"> The NFCSO did not require certified establishments to ensure zero tolerance requirements for carcasses to be free of fecal material, ingesta, and milk are met prior to entering the chill cooler. The NFCSO inspection personnel did not conduct offline verification of zero tolerance requirements to ensure carcasses are free of fecal material, ingesta, and milk prior to entering the chill cooler. 	
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System	
<ul style="list-style-type: none"> At three of the five audited establishments, the hazard analysis identified the biological hazard of <i>Salmonella</i> as likely to occur with no associated critical control point (CCP) to control the identified hazard. At three of the five audited establishments, the written HACCP plan did not meet NFCSO requirements to include written procedures or frequencies for all required verification procedures. At one audited establishment, the written HACCP plan did not meet NFCSO requirements to include all required parts of corrective actions for a zero-tolerance fecal material, milk, and ingesta CCP, a repeat finding of the last FSIS audit in 2017. 	

The FSIS auditor verified through interviews and review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the 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.

The NFCSO is the CCA of Hungary's meat inspection system and is organized and administered by the national government's Minister of Agriculture. The FSIS auditor confirmed through interviews and record reviews that there have been no major changes in NFCSO's organizational structure since the previous FSIS audit conducted in 2019. NFCSO represents the first level of legal authority of the inspection system and provides overall regulatory oversight to the establishments that are certified to export products to the United States. Additionally, NFCSO directs the Department of Food Chain Safety of the County Government Offices (CGO) that represents the second level of inspection and the Food Chain Safety and Animal Health Unit of the District Government Offices (DGO) that represents the third level of inspection to develop and implement plans, procedures, and guidelines for meat inspection. The DGOs directly oversee certified establishments within their jurisdiction.

The FSIS auditor verified through review of programs and records that NFCSO has procedures in place to ensure an effective level of oversight is maintained and official government inspectors are present to conduct carcass-by-carcass inspections continuously and processing inspection activities at least once per shift. The CGOs and DGOs work in conjunction to assign government inspection personnel to eligible establishments to ensure staffing levels are adequate, program verification tasks are completed according to schedule on a daily and shift-by-shift basis, and that official sampling tasks are performed for products that will be certified for export to the United States. A duty roster is maintained with extra personnel who are available to ensure equivalent requirements of ante-mortem, humane handling, post-mortem, processing, and export certification are performed by official veterinarians (OV) and official auxiliary inspection personnel.

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

The document Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America describes the establishment certification procedure for eligibility to export to the United States. Establishments that intend to export to the United States must apply to the CGO. The CGO then conducts the initial export approval review through a comprehensive establishment audit, which consists of a review of the establishment's documentation including HACCP, sanitation, and sampling documents as well as onsite visits to the establishment to verify that all regulatory requirements specific to the United States have been met. If approved for export to the United States, county officials inform NFCSO, which then conducts an audit of the establishment. NFCSO has the sole authority to grant final certification of a new certified establishment or to allow an existing certified establishment to maintain its eligibility to export to the United States. NFCSO completes the U.S.A. Central Checklist every 6 months to verify that all requirements are being met. NFCSO's Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America requires that source materials used can only originate from certified establishments that are certified as eligible to export to the United

States. The NFCSO document describes that product produced at one establishment and exported by another is accompanied by a pre-export certificate indicating compliance with export requirements. The FSIS auditor verified these procedures and did not identify any findings.

The OV ensures the inspection and certification of product for export in accordance with FSIS requirements. The OV inspects product integrity of packages, labeling of packages, temperature of product, and quantity to be certified. During the export certification process, the OV can verify product was produced for United States export and is eligible based on the product information provided by the establishment (i.e., daily production records). The OV certifies the shipment by use of an official stamp unique to that OV and their signature on a bilingual health certificate. The FSIS auditor verified through interviews and records reviews that those controls are in place to prevent misuse or fraudulent activities during the export certification process. NFCSO can track export certificates issued for a specific country. This tracking system relies on the issuance of a unique identification number for each certificate and the maintenance of records that includes a signature card for each authorized veterinarian. In addition, the FSIS auditor verified that OVs verify that establishments have a recall plan in place and can trace products forward in the event of a recall, as required by NFCSO.

A review of establishment pre-shipment review records is performed by the OV before issuing an export health certificate. Pre-shipment review includes the review of the laboratory test results, including the microbiological sampling results for products and food contact surfaces and the verification of the proper labeling of the products. Certification of product for export does not occur until microbiological test results of the establishment or official NFCSO microbiological testing results are received as acceptable. Under NFCSO's routine residue monitoring program, and when an OV suspects or chooses to sample an animal for any chemical residues under the targeted testing program based on observations during ante-mortem or post-mortem inspections, that carcass and parts are held pending acceptable test results.

The FSIS auditor verified through interviews and record reviews with NFCSO that all inspection personnel or licensees are paid by the government. The government inspectors at the approved certified establishments are commissioned either directly by the local CGO or by the subordinate District Office. Only OVs are authorized to perform all aspects of carcass inspection, including final disposition in establishments certified as eligible to export to the United States. The government veterinarian inspectors consist of official auxiliaries and OVs. Both are, by definition, directly appointed and employed by the competent authority (CA). Official auxiliaries work under the authority, supervision, and responsibility of an OV. Final disposition of carcasses is the exclusive responsibility of the OV. A performance evaluation of employees is required twice a year for civil servants with a performance rating provided by the supervisor on a yearly basis.

The FSIS auditor verified through interviews and record reviews that the CGO and DGO employees have met pre-employment requirements of NFCSO including a veterinary degree for OVs, and specialized experience for official auxiliary personnel. The NFCSO also indicated in interviews that ongoing training sessions per NFCSO Training regime and procedures for official inspection personnel overseeing U.S. eligible certified establishments were held at least every 2 years which included specialized training pertaining to FSIS requirements including humane

handling and slaughter of livestock, ante-mortem inspection, post-mortem inspection, Sanitation standard operating procedures (Sanitation SOPs), HACCP system requirements, control of *Lm* in the post-lethality environment, lethality in RTE fermented and dried products, hygiene and sanitation performance standards, sample collection procedures for microbiological testing at slaughter and microbiological testing at processing, and the export certification process. NFCSO also indicated that any changes in FSIS requirements are made available through its intranet website and are also communicated directly to official inspection offices and establishments through email, by way of training events, and through mailing of hard copies.

NFCSO provides direct oversight of government-operated laboratories, which are responsible for analysis of all official chemical residue and microbiological samples. NFCSO requires laboratory accreditation through independent audits and a yearly accreditation audit by the accrediting body, Hungarian National Accreditation Authority according to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. This accreditation process also includes a review of mandatory competency testing completed by each laboratory. NFCSO verifies that laboratories continue to meet the minimum ISO standards through the evaluation of audit reports and copies of the accreditation. The FSIS auditor reviewed the most recent accreditation reports available for the National Residue Laboratory and National Microbiology Laboratory and confirmed that any identified findings were addressed in a timely manner.

The FSIS auditor verified through interviews with OV's that sample schedules are received from the laboratory providing the specific details for every sample to be submitted. Sample tissues are then collected according to test instructions and packaged by the OV's. Information on the requested sample is entered into the NFCSO laboratory system by the OV and included with the sampled tissues, which are packed, sealed, and shipped through a NFCSO official government paid couriers. These couriers have routine routes to pick up samples directly from certified establishments, thereby maintaining official government control of all samples until the samples are delivered to the laboratory for analysis. The FSIS auditor verified through interviews and record reviews that the Budapest laboratory reports results of analyses directly to NFCSO headquarters, the CGO, the DGO, and the in-plant OV where the sample originated.

The NFCSO National Reference Laboratory (NRL) for Microbiology is the only laboratory in Hungary that is accredited for the performance of the FSIS Microbiology Laboratory Guidebook method for the detection of *Lm*. Testing of official verification samples on *Lm* are exclusively performed by the NRL. Sampling results must be sent via email directly to NFCSO Food and Feed Safety Directorate.

The auditor verified that Hungary's pork inspection system is organized and administered by the national government, and that NFCSO inspection officials are assigned to enforce the laws and regulations governing pork products.

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.

The FSIS auditor verified through interviews and record reviews that in-plant OV's are required to conduct humane handling and slaughter procedures in accordance with NFCSO issued Decree No. 140/2012 (XII.22) and Control System for Animal Welfare as the enabling documents for Council Regulation (EC) No. 1099/2009, which describes the responsibilities and official controls for humane handling and slaughter of livestock. NFCSO requirements for OV's include inspection verification of proper repair and maintenance of holding pens and alleyways, verification of proper handling of livestock prior to slaughter, and evaluation of the stunning effectiveness and sticking procedures. NFCSO CGO inspections in slaughterhouses are performed according to a risk-based control plan by the CGO using checklists issued by the CA. The Quarterly inspection protocol for the on-site inspection of export facilities (checklist) Circuit Supervisor On-Site Survey Checklist includes a section for animal welfare verification. The USA Central Checklist (completed every 6 months) also includes an animal welfare verification section. The FSIS auditor's remote audit activities confirmed that humane handling and slaughter of livestock are conducted in accordance with NFCSO requirements.

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

The FSIS auditor verified through interviews and record reviews that OV's perform ante-mortem inspection on every shipment of swine animals prior to slaughter at a certified establishment in accordance with Regulation (EU) 2017/625 and implemented through Hungary's NFCSO Official Guide. Ante-mortem inspection must take place within 24 hours of an animal's arrival at a slaughterhouse, and less than 24 hours prior to slaughter. Additionally, any swine that arrive dead are condemned as ineligible for human consumption and are subject to veterinary inspection and further testing for African swine fever as an additional surveillance activity. No concerns arose regarding NFCSO's ante-mortem inspection procedures.

NFCSO requires that only pork products that are not restricted for export to the United States are exported. This is verified by the OV monitoring the USDA APHIS website and verifying

restrictions under 9 CFR 94 prior to signing an export certificate every time a certificate is requested. Export requirements including disease restrictions are listed on the NFCSO website. Only those pork products that have been previously identified by NFCSO as meeting both FSIS and APHIS requirements can be certified for export to the United States.

The FSIS auditor verified through interviews and record reviews that each audited establishment is staffed with a sufficient number of government inspection personnel to conduct post-mortem inspection activities. This includes in-plant inspection verification of proper presentation and identification of carcasses and parts; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts in accordance with the NFCSO Official Guide. In the case of animals designated for United States export, additional requirements, such as incision of lymph nodes, are detailed in the Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. All carcasses railed out during post-mortem inspection must be re-inspected by an OV prior to being released back into the process. The FSIS auditor confirmed that post-mortem inspection is conducted continuously during slaughter operations in accordance with NFCSO requirements.

The FSIS auditor verified through interviews and record reviews that the OVs verify certified establishments meet the requirements of NFCSO's Hungarian Decree No. 45/2012, Health rules concerning animal by-products of animal origin not intended for human consumption, which grants NFCSO and the county government authority to verify inedible material disposal in certified establishments. Certified establishments are responsible for the handling, marking and storage of inedible materials with controls to ensure that inedible carcasses and parts are clearly identified. OVs verify establishment controls of condemned material handling as part of their routine inspection verification procedures. The OVs continuously verify compliance with the establishment's collection, transport, storage, handling, processing and use or disposal of animal by-products for which the establishment is responsible. NFCSO complete the Checklist for on-site inspection of facilities approved for U.S. exports by the Central Authority every 6 months (USA Central Checklist), which includes a section for the verification of disposition of contaminated product.

The FSIS auditor verified through records review and interviews that the following supervisory reviews occur at the specified frequency: NFCSO personnel perform reviews twice annually, CGO personnel perform quarterly reviews, and the OV of the establishment performs monthly reviews. Reviews performed by NFCSO, CGO, and DGO officials include evaluation of establishment actions in response to the previous supervisory review, onsite survey, or audit of the establishment during operations, and the DGO documentation of inspection activities, review of facility conditions, Sanitation SOPs, and HACCP programs and records, establishment and inspection testing programs and records, and traceability records of products. Additionally, the OV conducts performance reviews twice a year for the in-plant OV who is responsible for oversight of all activities within a certified establishment. Any observations of noncompliance during reviews are also documented, requiring the certified establishment to document corrective actions, which are subject to verification. The FSIS auditor verified these NFCSO procedures during the audit through interviews and review of records.

The FSIS auditor verified through interviews and record reviews that NFCSO requires certified establishments to properly label products according to the NFCSO document, Information about U.S.A. Export Labeling of Products and Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. The OV verifies that products certified to export to the United States are produced and stored separately by time or space from products destined for export to other markets. The FSIS auditor was informed that in-plant inspection personnel conduct labeling verification of products destined for export to the United States for each shipment of product to ensure that the information on the product labels is complete, accurate, and meets FSIS labeling requirements.

The FSIS analysis and remote verification activities indicate that NFCSO maintains the legal authority and a regulatory framework that is consistent with the criteria for this component and therefore continues to meet the core requirements.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The FSIS auditor verified through interviews and record reviews that NFCSO requires certified establishments to comply with the document, Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. Certified establishments are required to develop, implement, and maintain Sanitation SOPs to ensure operations occur under sanitary conditions and prevent the contamination of products. The document requires certified establishments to have written programs and include procedures conducted before and during production and to identify the frequency at which procedures are conducted. NFCSO also requires certified establishments to take corrective actions, including disposal of contaminated product, restoration of sanitary conditions, and measures to prevent recurrence of product contamination; these last measures include evaluation and modification of the written Sanitation SOP programs. Certified establishments must also maintain daily Sanitation SOP records of implementation, monitoring, and corrective actions.

The NFCSO official verifies that SPS and Sanitation SOP requirements are met by each certified establishment according to NFCSO's document Official Guide. The NFCSO Official Guide also provides instructions to government inspectors to verify specific facility requirements consistent with 9 CFR 416.1 to 416.5. These requirements include general sanitary conditions, adequate ventilation, adequate lighting, water potability, proper conveyance of sewage, pest control, and adequate condition of walls, floors, and ceilings. The verification frequency for each of these components is generated by a computer program that evaluates risk factors such as product type, establishment size, results of previous checks, time elapsed since the last inspection of basic hygiene, interior design, and maintenance requirements. NFCSO Official Guide also requires the OV's to verify implementation of Sanitation SOP programs once per shift. Pre-operational sanitation verification inspection is performed by the OV on establishment equipment prior to

operations. The OV conducts pre-operational sanitation verification on a daily basis prior to production of product designated for export to the United States in accordance with NFCSO's established procedures. The FSIS auditor verified these NFCSO procedures during the audit through interviews and review of records.

NFCSO Letter No. 5200/1158-66/2019 requires certified establishments to develop, implement, and maintain written procedures to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. Certified establishments must maintain daily records sufficient to document implementation and monitoring of procedures that must be incorporated in their HACCP plan. The FSIS auditor verified through interviews and review of records that the OVs routinely perform verification of sanitary dressing procedures. Off-line government inspection involves an examination of both the outer and visceral surfaces of every carcass for fecal material, ingesta, and milk, paying particular attention to predilected sites of possible contamination. If any (condemnable) defect is found, the carcass is moved to a separating line immediately.

The FSIS auditor verified through interviews and review of records that NFCSO requires the OVs to verify certified establishments follow zero tolerance requirements for fecal material, ingesta, and milk as required by NFCSO Letter No. 5200/1158-66/2019. The OVs perform zero tolerance checks and document results during each shift.

The FSIS analysis and remote verification activities indicate that NFCSO requires operators of certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs and sanitary dressing procedures. FSIS concluded that NFCSO continues to meet the core requirements for this component.

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.

NFCSO conducts an audit on an annual basis at each certified establishment to evaluate the HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews. The FSIS auditor verified through interviews and record reviews that NFCSO requires certified establishments to develop and implement a HACCP system in accordance with NFCSO's document Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. Officers from the NFCSO, CGOs and DGOs conduct audits at the stated frequencies of annually, quarterly, and monthly, respectively, that evaluates the HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews as part of an audit at each certified establishment.

Certified establishments are required to meet the HACCP requirements set forth within the NFCSO Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. The OV's follow the NFCSO Official Guide, as the basis for performance of NFCSO verification activities in certified establishments. The NFCSO Official Guide provides the inspector with a list of questions to consider while reviewing and verifying that each of the seven principles of HACCP was followed by the establishment while preparing the HACCP plan. The NFCSO Official Guide also lists the four parts of HACCP corrective actions that are required in response to a deviation. The FSIS auditor verified through interviews and record reviews that the OV develops an annual inspection plan to schedule audits, and daily and weekly inspections. Results of inspections and verifications are documented and reviewed by NFCSO and CGOs during their respective audits.

The FSIS auditor reviewed documents to verify that OV's verify CCPs according to the monitoring plan. Documents reviewed included performance of daily zero tolerance checks, OV reviews of establishment pre-shipment reviews and laboratory results, and verification of certified establishment CCPs by either review of records, observations by the OV, or by direct observation of establishment monitoring of the CCP. NFCSO Official Guide also provide further instructions on how OV's are to verify the product flow chart and description, hazard analysis, HACCP plan, monitoring, verification, corrective actions, recordkeeping, and pre-shipment reviews. The FSIS auditor verified that if a non-compliance was observed, the certified establishment is provided notification, the findings are documented, and the certified establishment must take corrective actions which are then reviewed by the OV in addition to the NFCSO and CGOs.

The FSIS analysis and remote verification activities indicate that NFCSO requires operators of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that NFCSO continues to meet the core requirements for this component.

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.

Prior to the audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed Hungary's 2022 National Monitoring Sampling Plan (NMSP), associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Hungary's official chemical residue testing program. The NMSP specifies the analytes included in the testing program, the method of analysis to be used, the matrix to be collected, and the total number of samples to be collected and tested.

The FSIS auditor verified that the NMSP is developed and administered by NFCSO to plan and manage the testing of carcasses and parts for chemical residues and contaminants in pork

products. The NRL for chemicals in Budapest in coordination with NFCSO are responsible for planning, implementation, and coordination of the NMSP on a yearly basis in accordance with Commission Directive 96/23/EC. The yearly sampling plan is developed based on the number of animals slaughtered and results of sampling during the previous year with a distribution of analyses performed for several categories including substances having an anabolic effect, unauthorized substances, veterinary drugs, and environmental contaminants. The Budapest laboratory sends sample requests based on the NMSP to CGO who then provides the request to OV's at each DGO.

The OV's indicated during interviews that any carcass sampled for chemical residue testing is identified and segregated to ensure that the specific carcass and its parts are held pending acceptable test results and that these carcasses and parts are excluded from export to the United States. The acceptability of test results is based on EU requirements and FSIS identified banned substances with zero tolerance levels and substances with maximum residue levels permitted in foodstuffs. If a maximum residue level is exceeded or a prohibited substance is detected, NFCSO initiates an investigation into the cause. NFCSO then requires that each certified establishment evaluate test results to determine if product meets all United States requirements prior to requesting export certification. The FSIS auditor verified through interviews that based on these NFCSO requirements that all establishments currently certified to export to the United States have procedures in place to separate and exclude all carcasses and parts tested for residues and to ensure the tested product is not exported to the United States. NFCSO addressed hold and test requirements through NFCSO Letter No. 5200 95_3 2020, which states that animal carcasses sampled for residual toxicology may not be included in the production of export goods destined for the United States market.

The FSIS auditor verified that in the event a result is violative, NFCSO NRL chemical laboratory immediately notifies NFCSO headquarters, the CGO, the DGO, and the in-plant OV who submitted the sample to ensure all affected product is identified. If a maximum residue level is exceeded or a prohibited substance is detected, NFCSO initiates an investigation into the cause. In addition, the movement of livestock from the farm of origin is halted until the investigation can be satisfactorily completed.

The FSIS analysis and remote verification activities indicate that NFCSO has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in pork products destined for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2019. FSIS concludes that NFCSO continues to meet the core requirements for this component.

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 are safe and wholesome.

Prior to the audit, FSIS reviewed Hungary's national microbiological sampling and testing programs, laboratory methods of analysis, and SRT responses outlining the structure of NFCSO's microbiological verification sampling and testing programs. The FSIS auditor confirmed there have not been any major changes to NFCSO's official microbiological verification testing programs or requirements regarding pork products exported to the United States since the previous FSIS audit conducted in 2019.

The FSIS auditor verified through interviews and record reviews that NFCSO requires certified establishments follow Commission Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses. Per Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America, establishments must perform sampling of swine carcasses at pre-evisceration and at post-chill, consistent with FSIS requirements in 9 CFR 310.18, as well as sampling required by Commission Regulation (EC) No. 2073/2005. Certified establishments must take actions based on test results and immediately notify the OV of any single test result or a trend of test results requiring action. The OVs perform a review of the certified establishment's test program. The NFCSO Official Guide contains a checklist of activities the inspector verifies, including review of the sample plan, sampling frequency, sampling procedures, test methodology, results, analysis of results, and decision-making based on results and records of the testing program.

The FSIS auditor verified that NFCSO follows Commission Regulation (EC) No. 2073/2005 to implement a national *Salmonella* testing program that verifies process controls in swine slaughter operations for chilled carcasses. The national *Salmonella* testing program is implemented by OVs performing in-plant sampling and an NFCSO microbiological laboratory performing analysis of the samples. The frequency of sampling is based on the volume of the exported products. If a certified establishment fails three consecutive sample sets, it is removed from the list of certified establishments eligible to export to the United States. The suspension remains in effect until the certified establishment identifies the cause, takes proper corrective actions and preventive measures, and achieves the performance standard set based on the number of samples tested (n) and the maximum number of positives to achieve the standard (c). NFCSO's *Salmonella* performance standard for swine is consistent with FSIS' previous standards. The NFCSO Official Guide requires *Salmonella* sponge samples be collected once per week. The frequency can be reduced to every other week if the establishment has satisfactory results for 30 consecutive weeks. NFCSO verifies during supervisory reviews done twice a year that certified establishments are reducing and controlling *Salmonella* in raw meat.

The FSIS auditor verified through interviews that the OVs review and verify that certified establishments institute testing programs to ensure control and prevention of adulteration by *Lm* in the post-lethality production environment. Certified establishments must meet requirements described in the Procedures for the Export of Foodstuffs of Animal Origin from Hungary to the United States of America. NFCSO requires that *Lm* and *Salmonella* cannot be detected in product and that products do not come in contact with surfaces contaminated with *Lm*.

The FSIS auditor verified the NFCSO implementation of sampling for *Lm* and *Salmonella* in accordance with the document US Monitoring Surveys 2022, which provides the NFCSO sampling plan for food contact surfaces, environmental surface swabs, and product samples

specific to each certified establishment. These samples are collected and submitted by the government inspector and are tested exclusively by NFCSO laboratories. A zero tolerance is applied for *Lm* when the product is intended for export to the United States. All RTE products currently produced and certified for export to the United States are included in the NFCSO sampling plan. The 2022 sampling plan indicates the frequency of each establishment, with higher volume establishments being sampled more frequently.

The FSIS analysis and remote verification activities indicate that NFCSO conducts microbiological sampling and testing programs to ensure that pork products are safe and wholesome. There have not been any POE violations related to this component since the previous FSIS audit. FSIS concludes that NFCSO continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held July 21, 2022, by videoconference with NFCSO. The FSIS auditor concluded that Hungary's pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. NFCSO has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, NFCSO has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report

HUNGARIAN COMMENTS TO DRAFT AUDIT REPORT**1.) Bottom of Page No 5 (within the last paragraph):**

„NFCSO completes the U.S.A. Central Checklist every 6 months to verify that all requirements are being met.”

Hungarian comment:

Kindly note that as of now, 6-monthly inspections conducted by the central authority (NFCSO) are documented in the form of a so-called „official record”. There is a unified format for said document and the information is grouped by the inspected areas (such as general information, the activities to be inspected and so on). A central checklist specifically used for US-export related inspections is foreseen to be ready for the inspections of 2023, however, as of now, there is no such central checklist.

There is a general, non-US specific central checklist provided by the NFCSO – the so-called EÜER, as it was mentioned during the audit. This is filled out by the county-, or district-level competent authority. Further to that, on district level, usually a so-called pre-op inspection checklist is equally filled out. On county level, a US-export specific checklist is filled out as well. These were all presented at the audit.

2) Middle section of Page No 6, last sentence of paragraph 3:

„Under NFSCO’s routine residue monitoring program, and when an OV suspects or chooses to sample an animal for any chemical residues under the targeted testing program based on observations during ante mortem or post-mortem inspections, that carcass and parts are held pending acceptable test results.”

Hungarian comment:

As set out in the document on the protocol of the export procedure and equally communicated, no carcass that is sampled for the purpose of monitoring (chemical residue sampling) can go to U.S. export. These carcasses are all excluded from U.S. export.

We noted that the statement was updated on page 13 in accordance with the aboves.