



United States Department of Agriculture

Food Safety and
Inspection Service

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Avenue, SW.
Washington, D.C.
20250

Dr. Taina Aaltonen
Ministry of Agriculture and Forestry
Helsinki, Finland

Dear Dr. Aaltonen,

The United States Department of Agriculture Food Safety and Inspection Service conducted a remote ongoing verification audit of Finland's meat inspection system from August 31 through September 27, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Finland are included as an attachment to the final audit report.

For any questions regarding this audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Catlin", written over a light blue circular stamp.

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
FINLAND

AUGUST 31–SEPTEMBER 27, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
RAW PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 1, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine equivalence verification audit of Finland conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from August 31–September 27, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using video conferences for interviews and records review. The purpose of the audit was to determine whether Finland's food safety inspection system governing raw 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. Finland currently exports raw 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.

The FSIS auditor concluded that Finland's raw pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Finnish Food Authority (FFA), as the Central Competent Authority (CCA) has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, FFA has implemented requirements for microbiological and chemical residue testing programs that are organized 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 Finland's food safety system from August 31–September 27, 2021. The audit began with an entrance meeting held via videoconference on August 31, with representatives from the Central Competent Authority (CCA)—Finnish Food Authority (FFA). Representatives from the FFA 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. Finland is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products ¹
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Finland as subject to African swine fever (ASF) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8, classical swine fever (CSF) requirements specified in 9 CFR 94.31, and foot-and-mouth disease (FMD) requirements specified in 9 CFR 94.11.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Finland's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditor conducted interviews and reviewed records to determine whether Finland's food safety inspection system governing raw 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 three-year period, in addition to information obtained directly from FFA through the SRT.

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

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 from FFA headquarters and two regional areas, and government verification records from two local inspection offices located within the certified slaughter establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled three meetings each week over a four-week period with an exit meeting on week five. 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 SRT and supporting documentation.

Finland currently has four establishments certified to export to the United States, with two slaughter establishments producing products which are then exported through separate certified cold storage facilities. The two slaughter establishments selected for the remote audit produce raw intact pork products for export to the United States.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. The FSIS auditor assessed FFA'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 microbiological laboratory and one residue laboratory to verify that these laboratories provide adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • FFA, Helsinki
	Regional	2	<ul style="list-style-type: none"> • FFA, Southern Finland Meat Inspection Area • FFA, Central Finland Meat Inspection Area
Laboratories		2	<ul style="list-style-type: none"> • National Reference Laboratory, (government residue), Helsinki • HKScan Finland Ltd., (private microbiological), Vantaa
Pork slaughter establishments		2	<ul style="list-style-type: none"> • Establishment No. 18 HKScan Finland Ltd., Forssa • Establishment No. 22 Atria Ltd., Nurmo

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 Livestock 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 Finland's inspection system for raw 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 May 1, 2018 to April 30, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 2,332,092 pounds of raw intact pork products exported by Finland to the United States. Of these amounts, additional types of inspection were performed on 447,844 pounds, including physical examination, chemical residue analysis and microbiological pathogen testing. No pork products were rejected as a result of these additional inspections, however 1,674 pounds were refused entry for shipping damage issues.

The previous FSIS audit in February of 2019 identified the following findings:

Summary of Findings from the February 2019 FSIS Audit of Finland	
Component One: Government Oversight (e.g., Organization and Administration)	
<ul style="list-style-type: none">• The Central Competent Authority (CCA) allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.	
Component Four: Government Hazard Analysis and Critical Control Point (HACCP) System	
<ul style="list-style-type: none">• The CCA has regulatory requirements for zero tolerance of feces and ingesta; however, there are no written requirements for zero tolerance of milk on pork carcasses and parts.	

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 Finland's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/inspection/import-export/international-reports/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 FFA is the CCA of Finland's meat inspection system and was formed in 2019 with the merger of the Finnish Food Safety Authority, the Finnish Agency for Rural Affairs, and parts of the National Land Survey of Finland's Center for Information Technology. FFA has the overall responsibility for regulation of pork products and activities related to their inspection and export certification through national legislation including the Finnish Food Act 297/2021, the Ministry of Agriculture and Forestry Regulation 315/2021 and the Ministry of Agriculture and Forestry Regulation 318/2021. The FSIS auditor confirmed through interviews that there have been no major changes to the organizational structure with the exception of an increase in the number of area meat inspection units from three to four.

Official controls are administered through FFA's Food Chain Division, Food Safety Department, Meat Inspection Unit which provides oversight of the Official Veterinarians (OVs) and Official Auxiliaries (OAs) who are assigned to each individual certified slaughter establishment. In certified cold storage facilities, a supervisory OV or a Municipal Veterinary Officer (MVO) is assigned overall responsibility for official controls and for performance of export certification of pork products. FFA ensures 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. The FSIS auditor verified through review of programs and records that FFA 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 FSIS auditor verified through interview that OVs and OAs are employed and paid directly by FFA, while MVOs are employed and paid by local Municipal Food Control Authorities.

The FSIS auditor verified through interviews and record reviews the process for certification of an establishment as eligible to export pork products to the United States. An establishment must apply to FFA which then performs a document review of the establishment's food safety system summary inspection results within FFA's food control inspection information system called Oiva. If the establishment is meeting European Union (EU), European Commission (EC) and national requirements, FFA Export Section conducts an audit of the establishment. During the onsite inspection of the establishment, FFA evaluates the HACCP control system and whether the establishment has implemented FSIS requirements in their programs. If the outcome of FFA audit is acceptable, FFA will request that FSIS list the establishment as certified to export to the United States. The certified establishment would then be included in trainings held regarding United States export topics, subjected to regular OV or MVO export verification controls, and

FFA Export Section would conduct audits according to the schedule based on the type of certified establishment.

An FFA senior officer of the Export Section conducts audits of each certified slaughter establishment six times per year, and each certified cold storage facility two times per year. During an audit, the senior officer audits both FFA OV performing verification of establishment controls and the establishment's food safety systems and records. After completion of an audit, the OV writes and issues an inspection report, and the senior officer writes and issues an audit report. The establishment must respond and correct any findings of nonconformance, after which the OV and the senior officer perform follow-up review of establishment actions during the next audit. In the case of severe findings that could affect product safety, an enforcement measure consisting of a Notice of Intent to Delist (NOID) is issued by the senior officer, whereby FFA provides the establishment 30 days to correct an issue or have their export certification removed. An FFA senior officer must perform a follow-up review within 31 days to verify the establishment has corrected all non-conformances documented in the NOID. There have been no enforcement actions since the last FSIS audit.

FFA ensures that only products that have been inspected and certified as eligible for export to the United States are issued a veterinary health certificate. An exporter is responsible for providing all information in order for the veterinarian to certify that the pork products meet United States export requirements. The veterinarian verifies all requirements have been met prior to issuance of the signed and stamped health certificate. A FFA OV issues the veterinary health certificate if the export takes place from a certified cold storage facility located within the OV's assignment. An MVO will issue the veterinary health certificate at a certified cold storage facility that is located off site from a certified slaughter establishment. Health certificates are issued on security paper which is individually numbered and managed by an FFA tracking system. Security papers must be kept in locked cabinets under OV or MVO control, with copies and records of use on file for a minimum of five years.

Certified slaughter establishments audited conduct species identification sampling annually, with the OV documenting verification of species identification on a monthly basis. EU and national regulations require traceability of food products, specifically Regulation (EU) No 1169/2011, and Decree of the Ministry of Agriculture and Forestry on food hygiene 318/2021. FFA only permits pigs from farms in Finland to be slaughtered in establishments approved for exporting meat to the United States. Meat from slaughterhouses not certified for export cannot be used and cannot enter an approved establishment without control programs. The FSIS auditor verified through interviews that OVs are aware of requirements for disease status as outlined by APHIS. Products not eligible for export to the United States are identified and kept both physically separated from eligible products and identified as not eligible for export within computer tracking systems. FFA OVs verify slaughter establishment controls and are continuously present each day during slaughter and cutting operations.

Regulation (EC) No 178/2002 requires all food business operators to withdraw or recall food that is not in compliance with food safety requirements. The OV verifies that each certified establishment develops and maintains a recall plan. Certified establishments are required to inform FFA of the shipment of adulterated product through use of the form entitled Notification

of Recall of Food/Food Contact Material. FFA has a mechanism in place to notify FSIS of the shipment of adulterated products. There have been no recalls of pork products exported from Finland since the last FSIS audit.

FFA uses Regulation (EU) No 2017/625 as the basis for designation of an accredited or official laboratory. In order for a laboratory to be listed and designated by FFA as an authorized or official laboratory, the lab must first be accredited by the Finnish Accreditation Service (FINAS). FINAS accredits laboratories according to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards. FFA receives FINAS audit results and will review each specific method of analysis for which a laboratory has applied for approval. After review and evaluation, FFA will list a laboratory as a designated official laboratory with the specific method that is approved for official analysis of samples. During the audit, the FSIS auditor verified through records review and interviews that laboratories performing analyses of officially required samples are accredited with FINAS and authorized as an official laboratory by FFA.

The FSIS auditor confirmed through record review that FINAS conducts an accreditation audit of the NRL on a yearly basis and requires laboratories to meet ISO/IEC 17025 standards. The FSIS auditor interviewed staff and reviewed documents from the NRL to verify adequate controls are in place for package integrity and FFA seals at receiving, use of recognized and approved analysis methods, calibration of laboratory equipment, ongoing control testing to verify methods and results of analyses are reported according to FFA procedures and systems. The FSIS auditor also reviewed internal employee training and proficiency requirements and the results of the most recent FINAS and internal audits.

The FSIS auditor verified through interviews and record reviews that FFA reviews the FINAS ISO 17025 accreditation reports for each laboratory, requires direct approval of the methods of analysis of each test and requires the laboratory to request prior approval for any new or an alternative method. The FFA also requires both authorized official laboratories to participate in proficiency testing on an annual basis.

Through record reviews and interviews, the FSIS auditor confirmed that the HKScan Finland Ltd. Laboratory is audited by FINAS for ISO 17025 accreditation on a yearly basis. The FSIS auditor verified the laboratory has received a *Salmonella* sampling schedule from FFA, and all results of analysis for *Salmonella* are reported through FFA reporting system. The FSIS auditor verified that the laboratory has appropriate programs in place and maintains records for all procedures and steps samples undergo, including receiving of the sample to ensure package integrity, tracking and documenting each step of the analysis process, calibrating equipment, internal employee training programs, and proficiency requirements specific to the analyses performed. The laboratory analysis method approved by FFA and currently in use for *Salmonella* testing is ISO 6579:1-2017. This method includes a positive control for every analysis performed.

FFA educational and training requirements for OV's and OAs are set within Regulation (EU) No 2019/624. The FSIS auditor verified through interviews and review of records that FFA has an

annual training plan in place and has conducted initial training for employees upon hiring as well as continual ongoing and refresher training of all employees. Employees are trained based on their specific job duties including ante-mortem, post-mortem, animal welfare and humane handling, transport of animals, export certification, sanitation, HACCP, and sampling techniques. Employees are also provided training about specific FSIS requirements including labeling, test and hold, and pre-shipment review.

The FSIS auditor confirmed through interview and review of records that due to previous FSIS audit findings, FFA has implemented changes in establishments certified for export to the United States. FFA now requires any carcass sampled for residue testing to be placed on hold until acceptable results are returned. The requirement for holding sampled carcasses is applicable to all official residue samples (routine and OV suspect samples) as well as any sampling performed by the certified establishment. FFA held training regarding this requirement with FFA staff, and certified establishments were informed of the change in FFA requirements.

The auditor verified that Finland's meat inspection system is organized and administered by the national government, and that FFA inspection officials are assigned to enforce the laws and regulations governing meat 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 each carcass and part; 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 establishments certified to export to the United States.

The FSIS auditor verified through interviews and record reviews that FFA requires an OV to perform ante-mortem inspection of each animal prior to slaughter. Ante-mortem inspection is carried out according to EU and FFA regulations implemented through procedures in FFA Guideline 5734/04.02.00.01/2020/2. 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. The OV may require an additional inspection at any other time as deemed necessary. The OV will determine if the health and welfare of the animal is compromised, any abnormality or disease condition which may affect the suitability of the animal for human consumption, and any use of prohibited or unauthorized substances. The OV also reviews food chain information of the animals being inspected including health status of the animal, region of origin, any prior veterinary treatments and associated withdrawal periods, and production data that may provide information on disease status of the animals. Any injured or non-ambulatory animal must be handled separately and is identified as not eligible for export to the United States.

FFA follows EU and FFA regulations regarding animal protections during transport, protection of animals during slaughter, and animal welfare to verify humane handling occurs from the initial starting point of moving animals from the farm through the process until animals are slaughtered. FFA requires certified slaughter establishments to appropriately stun or kill animals prior to the bleeding process, with no other procedures being performed to the animal before it is dead. Each slaughterhouse operator is required to have a written humane handling program including records of their own monitoring of the program controls. FFA OV's verify the establishment is following its own written programs and perform additional verification checks of holding facility conditions including unloading of transport vehicles, water availability in pens, movement of animals to slaughter, and stunning effectiveness. FFA OV's document results of their verification procedures, including any administrative or enforcement actions they take based on an observation of non-compliance.

The FSIS auditor verified through interviews and record reviews that post-mortem inspection of each swine carcass, head and viscera occurs according to FFA Guideline 18511/6 Official Control of Meat Establishments Approved to Export to the United States. Under supervision of OV's, the OAs perform carcass-by-carcass inspection by checking all external surfaces, surfaces of body cavities, and offal with incisions and palpations of carcasses, lymph nodes and offal according to the guidelines. FFA OAs identify (and place on a side rail) carcasses and parts with signs of disease for further inspection and disposition by OV's. Carcasses on the side rail cannot re-enter the production flow until an OV permits release of each carcass.

The FSIS auditor verified that FFA Guideline 18510/6 Requirements for United States Export Approved Meat Establishments provides certified establishments with requirements for the control of condemned materials. Certified establishments are responsible for the handling, marking and storage, with controls to ensure that materials are clearly marked. During transport materials must be accompanied by documentation and they are sent only to approved handling facilities. OV's verify establishment controls of material handling as part of their daily inspection verification procedures, and document results in the Oiva system control plan.

FFA regional managers of each of the four meat inspection units conduct control visits on a quarterly basis, providing oversight and guidance to the supervisory OV in each certified establishment. During the control visit, the regional manager performs and documents their evaluation by reviewing the certified establishment's compliance with FFA requirements as well as verifying the overall performance of OV's and OAs under the direct supervision of the supervisory OV. FFA senior officers from the Export Division also evaluate performance of the supervisory OV, OV's, and OAs during their audits, which are conducted six times yearly. The regional managers and senior officers both document results of their reviews, with any need for training or follow-up activities based on performance of the assigned FFA staff. Any observations of non-compliance are also documented, requiring a response from the certified establishment in writing with corrective actions. The OV's verify establishment corrective actions and the senior officer or regional manager also verify establishment corrective actions and improvements in FFA personnel performance during the next audit or control visit.

The FSIS auditor verified through interviews and record reviews that FFA requires certified establishments to properly label products and include product name, identification mark, country

of origin, establishment number, name and address of the establishment, net weight of the product and safe handling instructions. Certified establishments are required to provide labels to OV staff prior to their use on product intended for export to the United States. Any labels with claims must be approved by FSIS prior to their use by an establishment.

The FSIS analysis and remote verification activities indicate that FFA maintains the legal authority and a regulatory framework that is consistent with the provisions 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 FFA requires each certified establishment to develop, implement, and maintain written sanitation standard operating procedures (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 that FFA requires certified establishments to comply with requirements of SPS and sanitation SOPs in accordance with FFA Guideline 18510/6. The guideline requires establishments to develop, implement, monitor, document results, and maintain written programs effective in ensuring all operations including that storage occurs under sanitary conditions. The guideline specifies that establishment programs must include procedures conducted prior to the start of production (pre-operational) and measures taken during production (operational) to prevent products from becoming contaminated. An establishment's program must also include written measures regarding disposition of affected product, immediate actions to restore hygienic conditions and measures to prevent recurrence including evaluation and modification of the written sanitation SOP programs.

FFA Guideline 18511/6 requires regulatory oversight of the establishment's SPS, and sanitation SOP programs on a daily basis by the in-plant OVs. The FSIS auditor verified through record reviews and interviews that the OVs perform pre-operational inspections to verify establishment programs are effectively implemented to prevent insanitary conditions. Pre-operational inspection is performed by observing the designated establishment employee performing their cleanliness check, or by the OV performing their own check after the establishment has completed their daily check. The OV documents results of the verifications on their weekly control records with observations of any non-compliance documented on Annex 6 (non-compliance report) of FFA Guideline 18511/6.

FFA Guideline 18510/6 requires certified establishments to perform slaughter under hygienic conditions and FFA Guideline 18511/6 requires OVs to perform slaughter hygiene inspections to verify establishments maintain hygienic conditions. The FSIS auditor verified through interview and review of records that the OVs perform verification of sanitary dressing procedures. Certified establishments have written programs in place with specific procedures to be taken at each step of the slaughter process, including changing and sanitizing of knives between carcasses, handwashing, changing of gloves and washing of aprons. Certified establishments must also prevent cross contamination between carcasses and ensure that the surfaces of

equipment which contact each carcass, such as splitting saws, must be cleaned and disinfected as needed.

Through interviews and review of records, the FSIS auditor confirmed that FFA requires the OV's to verify certified establishments follow zero tolerance requirements for fecal material, ingesta and milk as required by FFA Guideline 18510/6. FFA OV's perform zero tolerance checks and document results on the weekly control record. OAs perform inspection of each carcass for fecal material, ingesta and milk during the post-mortem carcass by carcass inspection. Any carcass with contamination is required to be trimmed immediately or sent to the side rail for trimming, with reinspection of each carcass prior to movement back onto the production line. The FSIS auditor also verified through review of records and interviews that FFA has updated FFA Guideline 18510/6 to include milk as part of the zero tolerance requirement.

The FSIS analysis and remote verification activities indicate that FFA requires operators of certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, sanitation SOP's and sanitary dressing procedures. FSIS concluded that FFA 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 certified establishment develop, implement, and maintain a HACCP system.

The FSIS auditor verified through interviews and review of records that FFA requires certified establishments to develop and implement a HACCP system in compliance with the Guideline: HACCP System, Principles and Application 10002/2 and FFA Guideline 18510/6. A senior officer from FFA evaluates the HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews as part of the audit at each certified establishment.

FFA OV verifies HACCP requirements are met by each certified establishment according to FFA Guideline 18511/6. The FSIS auditor verified through interviews and record reviews that the OV makes a control plan which ensures verification of all critical control points (CCP) procedures of monitoring, verification and corrective actions over a one-month period. FFA guideline provides further instruction for how OV's are to verify the product flow chart and description, hazard analysis, HACCP plan, monitoring, verification, corrective actions, unforeseen hazards, recordkeeping and pre-shipment reviews. The OV documents results of verification checks on their weekly control form with non-compliances documented on Annex 6 (non-compliance report) of FFA Guideline 18511/6.

The FSIS auditor reviewed documents to verify that FFA OV's verify all CCPs according to their weekly control plan. Documents that were reviewed included records of OV performance of zero tolerance checks and results of OV verification of establishment CCPs by either review of records or direct observation of establishment CCP monitoring. The OV's indicated in interviews

that if a deviation was observed, they would take action to identify and control affected product, and they would also notify the certified establishment of the observation both verbally and in writing by documenting a non-compliance on an Annex 6 form. The OV would then review the establishment's corrective actions and written responses to ensure all HACCP requirements were satisfactorily met. Regional managers and senior officers would also review any CCP deviations and establishment corrective actions as part of their control visits or the audits they perform.

The FSIS analysis and remote verification activities indicate that FFA requires operators of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that FFA 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 include 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 remote audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed Finland's National Residue Control Plan (NRCP), associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Finland's chemical residue testing program.

The FSIS auditor verified that the NRCP is developed and administered by FFA to plan and manage the testing of live animals and carcasses and parts for chemical residues and contaminants in pork products. FFA's Food Safety Department, Chemical Food Safety Unit is responsible for planning, implementation and coordination of the NRCP on a yearly basis in accordance with EC Directive No 96/23/EU and Decision No 97/747/EC. The yearly sampling plan is developed based on the number of animals slaughtered during the previous year with a distribution of analyses performed for several categories including prohibited substances, veterinary drugs and environmental contaminants. FFA sends sampling schedules to the supervisory OV in each certified establishment.

The FSIS auditor verified through interviews with supervisory OVs that sample schedules are received from FFA for each year providing a monthly schedule with the specific details for every sample to be submitted. The OV randomly determines when each sample will be taken throughout each month. Sample tissues are then collected and packaged by the OAs who are under direct supervision of the OVs. Official forms indicating the requested analysis are included with the tissues which are packed in a bag that is closed with a numbered FFA seal. Packaged samples are shipped immediately in cooler boxes with freezing blocks and sent by express mail to FFA National Reference Laboratory (NRL) for analysis. The OVs 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 not eligible for export to the United States.

The FSIS auditor verified through interviews and record reviews that the NRL reports results of all analyses to FFA headquarters personnel and the OV in the certified establishment where the sample originated. The NRL informs FFA of all samples with findings of residue levels immediately, allowing FFA Control Department to then determine if a residue sample result is detected at a level that is violative of EU or United States requirements. The FSIS auditor also verified that FFA staff evaluate residue analysis results to determine an occurrence of a violative test result based on United States residue limit requirements.

The FSIS auditor verified FFA actions in the event a result is violative, FFA informs the supervisory OV at the certified establishment and the regional state administrative agency (RSAA) where the producing farm is located. The RSAA sends a veterinary inspector to perform an investigation at the producing farm and take actions to prevent further violations from occurring, including changes in animal management, or sanctions and penalties for the farmer if warranted. After notification of a violative result, FFA supervisory OV at the certified slaughter establishment will verify the safety of animals sourced from the same producer by performing targeted follow-up samples of carcasses from the same production farm.

The FSIS analysis and remote verification activities indicate that FFA 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 raw pork products destined for human consumption. FSIS concludes that FFA 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 require certain sampling and testing programs to ensure that raw pork products prepared for export to the United States are safe and wholesome.

The FSIS auditor verified through interviews and record reviews that FFA requires certified establishments follow Regulation (EC) No 2073/2005 regarding process hygiene criteria testing and analysis for carcasses. FSIS accepts *Enterobacteriaceae* testing as equivalent to testing for generic *E. coli*². Certified establishments conduct indicator organism testing on carcasses for aerobic colony count and *Enterobacteriaceae* and then take actions based on a test result which exceeds the upper limit (M), or a trend is determined based on test results above the lower limit (m). The OVs review establishment test programs, observe establishment sampling, and receive test results on a weekly basis and verify any investigations and corrective actions taken in response to results which indicate a loss of process control.

The Decree of the Ministry of Agriculture and Forestry on zoonoses 316/2021 provides regulations and requires FFA to develop an annual sampling plan for the control of *Salmonella* in

² FSIS notified eligible foreign countries of new regulations for U.S. swine slaughter establishments and continues to ensure that the countries implement equivalent sampling and analysis for microbial organisms for monitoring process control throughout slaughter and dressing operations consistent with U.S. requirements in 9 CFR 310.18.

slaughter facilities. FFA sampling plan identifies the number of each sample type performed at slaughter and processing facilities, including sampling of lymph nodes, carcass surface sponge swabs and random pork meat at processing. The FSIS auditor verified through interviews and record reviews of OVs that each certified establishment receives an instruction letter from FFA indicating the number of each type of *Salmonella* sample that the establishment is responsible for collecting and having analyzed. The required number of samples is assigned proportionally to establishments based on the prior year's slaughter totals.

Each slaughter establishment certified to export pork products to the United States submits samples to their own private microbiological laboratory, which is recognized by FFA as an official laboratory and authorized to perform required *Salmonella* and indicator organism carcass testing.

The authorized laboratory must immediately notify FFA of a positive test result and send the sample to the NRL for typing of the isolate. The FFA OV is also notified of the positive test result, and they begin the process of verifying establishment corrective actions which must include traceback of the source of contamination and intensified cleaning and disinfection of the slaughter and processing facilities. To verify the effectiveness of the intensified cleaning and disinfection programs implemented at the slaughter and processing facilities, an establishment is required to collect a minimum of 59 follow-up samples comprised of environmental surface swabs and, dependent on the sample type of the initial positive test result, either carcass swab samples or raw pork meat samples.

The FSIS analysis and remote verification activities indicate that FFA requires and verifies microbiological sampling and testing programs to ensure that meat products are safe and wholesome. FSIS concludes that FFA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held remotely on September 27, 2021, with FFA. The FSIS auditor concluded that Finland's raw pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. FFA has required that establishments certified as eligible to export raw pork products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, FFA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety 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



Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date Dnro/Dnr/DNo
24.01.2022 417/00.01.03.01.04/2022

Dr. Michelle Catlin
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ANSWER TO THE FOOD SAFETY AND INSPECTION SERVICE'S (FSIS) DRAFT FINAL REPORT OF A REMOTE AUDIT CONDUCTED IN FINLAND FROM AUGUST 31 THROUGH SEPTEMBER 27, 2021

Finnish Food Authority (FFA) wants to thank FSIS for its draft final report of the remote routine equivalence verification audit conducted in Finland from August 31 through September 27, 2021. We have now thoroughly reviewed this draft final audit report, and in this letter we would like to give some technical comments regarding the information in the draft final audit report.

General information

On October 21st, 2021 FFA's Export Section organized a training for all establishments approved for U.S. export and the local official inspection personnel at these establishments. The topic of the training was general information of the FSIS remote audit in Finland and some updates regarding U.S. pork export guidelines. The aim of the training was to ensure that all establishments and local official inspection personnel would have the same and up-to-date information of the remote audit conducted.

Technical comments regarding the information in the Draft Final Audit Report

On page 2 it is mentioned that remote audit meetings were scheduled over a five-week period. In fact, the remote audit period took place over four weeks.

According to page 5, FFA senior officer or OV must perform a follow-up review within 31 days to verify the establishment has corrected all non-conformances documented in the

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NOID, if a NOID is issued to the establishment. According to the FFA guideline 18511/6 on *Official control of meat establishments approved to export to the U.S.*, it is the FFA inspector, that is, the FFA Senior Officer, who issues the NOID or lifts it after their follow-up visit.

On the page 5 it is stated that the results and the level of compliance of FFA audits and inspections are also published on the Oiva website. More precisely, the results of control made by OV's to evaluate the compliance of the establishment with the national and EU requirements are published as an Oiva report on the Oiva website. The specific U.S. related control results are only given by OV for the establishment and by FFA Senior Officer for the OV, and not published for public on the Oiva website.

On page 5 it is mentioned that certified slaughter establishments conduct species identification sampling annually, with the OV documenting verification of species identification on a monthly basis. However, the slaughter establishments are no more required to take these samples annually. Instead, the OV must write on a monthly basis an assurance that no other species have been slaughtered in the establishment except for pigs. In addition, FFA still recommends, that establishments slaughtering pigs also conduct species identification annually, but it is not mandatory.

According to pages 12-13, OV's review establishment test programs, observe establishment sampling, and check test results on indicator organism testing on carcasses on a weekly basis. In fact, OV's get the test results to be checked weekly, but the test programs and sampling event are reviewed less frequently. It is instructed in the FFA guideline 18511/6 *Official control of meat establishments approved to export to the U.S.*, Appendix 3, that OV's should control the slaughter hygiene sampling by inspecting one sub-area per month. In addition, OV's can always check the results any time they see it necessary.

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RUOKAVIRASTO

Livsmedelsverket • Finnish Food Authority

Tämä asiakirja on laadittu ja allekirjoitettu sähköisesti.
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