United States Department of Agriculture

Food Safety and
Inspection Service

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

October 7, 2024

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

Dear Dr. Aaltonen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Finland's meat inspection system May 15—29, 2024. 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 the FSIS audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

FINLAND

MAY 15–29, 2024

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 3, 2024

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Finland conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) May 15–29, 2024. The purpose of the audit was to verify 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 properly 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.

FSIS 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 has required that establishments certified as eligible to export raw pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, FFA has implemented official 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 U.S. Department of Agriculture (USDA) conducted an onsite audit of Finland's food safety system May 15–29, 2024. The audit began with an entrance meeting held May 15, 2024, in Helsinki, Finland, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Finnish Food Authority (FFA). Representatives from FFA accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted May 29, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw 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. Finland 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

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Finland as subject to 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, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Finland's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews and reviewed records to verify 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, port-of-entry reinspection and testing results, specific oversight activities of government offices,

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

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 FFA 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 auditors reviewed administrative functions at FFA headquarters, one Food Safety Control office, and two Meat Inspection Unit offices within the slaughter establishments. The FSIS auditors evaluated whether the control systems in place that ensure the national system of inspection, verification, and enforcement are being implemented according to FFA requirements.

All four establishments certified to export to the United States were audited. This included two pork slaughter and processing establishments, and two cold storage facilities. The products these establishments produce and export to the United States include raw intact pork products.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors 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 auditors also visited one microbiological laboratory and one chemical residue laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Finnish Food Authority, Helsinki
	Local	1	• Food Safety Control, Seinäjoki
Laboratories		2	• Finnish Food Authority, Laboratory and Research Division—Chemistry Unit, (government) Helsinki • Atria Suomi Oy, Microbiology Laboratory, (private) Nurmo
Pork slaughter and processing establishments		2	• Establishment No. 18, HKScan Finland Ltd., Forssa • Establishment No. 22, Atria Ltd., Nurmo
Cold storage facilities		2	• Establishment No. S061101, Pakastamo Ltd./HKScan Finland Ltd. (Cold Storage), Forssa

		• Establishment No. S743109, Hahka Way/Botnia Freeze Ltd. (Cold Storage), Seinäjoki

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

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Finland's inspection systems 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 January 1, 2021, to December 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,969,935 pounds of raw intact pork from Finland. Additional types of inspection were performed on 219,507 pounds of raw pork, including physical examination and microbiological (*Salmonella*) and chemical residue analyses. There was no raw intact pork product rejected or refused for issues related to public health as a result of this additional testing; however, 6,711 pounds of raw intact pork were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

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/foreign-audit-reports.

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

The first equivalence component the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

FFA is the CCA of Finland's meat inspection system and has the authority and 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 auditors confirmed that there have been no major changes to the organizational structure since the previous FSIS audit conducted in 2021.

Official controls are administered through FFA's Food Chain Division, Food Safety Department, Meat Inspection Unit (MIU), which is divided into four inspection areas. MIUs provide oversight of official veterinarians (OVs) and official auxiliaries (OAs) that are assigned to each individual certified slaughter establishment. In certified cold storage facilities, the supervisory OV or a municipal veterinary officer (MVO) from the local food safety control office is assigned overall responsibility for official controls and for performance of export certification of pork products. The FSIS auditors verified through interviews that OVs and OAs are employed and paid directly by FFA, while MVOs are government employees paid by the local municipal food control authorities.

The FSIS auditors verified the process for certification of an establishment as eligible to export raw pork products to the United States through interviews and record reviews. When an establishment applies for certification to export to the United States, FFA performs a document review of the establishment's food safety system which includes summarized inspection results within FFA's food control inspection information system, called Oiva. If the result of the document review confirms the establishment is meeting all of the food safety system requirements, FFA's Export Section then conducts an audit of the establishment. During the onsite audit, FFA evaluates the HACCP control system and determines whether the establishment has implemented procedures that meet FSIS import requirements as part of their programs. If the outcome of the FFA audit is acceptable, FFA submits a request that FSIS list the establishment as certified to export to the United States.

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 auditors verified through direct observation and review of programs and records that FFA has procedures in place to ensure an effective level of oversight is maintained and that official government inspectors are present to conduct inspection of each carcass and its parts during slaughter operations and at least once per shift during processing operations.

FFA educational and training requirements for OVs, MVOs, and OAs are set within Commission Delegated Regulation (EU) 2019/624. The FSIS auditors verified through interviews and review of training records that FFA has initial training in place for government personnel upon hiring, as well as annual ongoing and refresher training of OVs, OAs, and MVOs. Government personnel are trained based on their specific job duties, including ante-mortem, post-mortem, animal welfare and humane handling, sanitation, HACCP, and sampling techniques. Government personnel are also trained on specific FSIS import requirements, and export certification of pork products, if assigned to export facilities.

Government personnel are authorized to take enforcement actions in establishments to ensure compliance with FFA requirements in accordance with FFA Guideline 18511/8, Official Control of Meat Establishments Approved to Export to the United States. Upon identification of deviation from FFA requirements, the OV or MVO provides oral feedback to the certified establishment followed by a written report of the observation. The OV or MVO could also issue a written noncompliance report, which requires the certified establishment to provide a written response of corrective actions within a specified timeframe. In the case of severe findings that could affect product safety, the enforcement measure of a Notice of Intent to Delist (NOID) is

issued, whereby FFA provides the establishment 30 days to correct an issue or have their export certification removed. FFA may also cancel an establishment's U.S. export certification if the establishment fails to correct noncompliances identified in a NOID, more than three NOIDs are issued in a 2-year period, or if the establishment has not fulfilled FSIS import requirements. FFA has not issued a NOID or suspension of eligibility to export to the United States since the previous FSIS audit conducted in 2021.

The FSIS auditors verified that an FFA senior specialist of the Export Section conducts audits of each certified slaughter establishment four times per year and each certified cold storage facility one time per year. Audits are designed to verify establishment controls and the establishment's food safety systems and records, with additional topics covered, including the establishment meets U.S. import requirements. After completion of an audit, the senior specialist writes a report of the audit, which is sent to the control staff of the audited establishment. Certified establishments must respond with corrective actions for any findings, after which the senior specialist performs a follow-up review during the next regular audit to verify corrective actions were implemented and effective.

The FSIS auditors verified through a review of records that FFA currently only allows pigs of Finnish origin to be slaughtered and processed in certified establishments. OVs at certified establishments document verification of species on a monthly basis. Pork from slaughterhouses not certified for export cannot be used and cannot enter an establishment without control programs in place to ensure adequate separation. The FSIS auditors verified through interviews that FFA personnel, including OVs and MVOs, 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. OVs verify slaughter establishment controls and are continuously present each day during slaughter and verify controls at least once per shift cutting operations.

The FSIS auditors verified through observation and review of records that 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 OV or MVO to certify that the pork products meet U.S. import requirements. The OV or MVO verifies all requirements have been met prior to issuance of the signed and stamped health certificate. An OV issues the veterinary health certificate if the export certification takes place at 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. Veterinary 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 5 years.

The FSIS auditors verified through interviews and direct observations that carcasses and their parts tested for chemical residues were clearly identified and segregated throughout the production process, including during cutting operations, and maintained separate from products eligible for export to the United States until acceptable results are received. FFA requires certified establishments to maintain traceability of products and develop and maintain a recall

plan. Certified establishments are required to inform FFA of the shipment of adulterated product. The FSIS auditors also verified that FFA has a mechanism in place to immediately notify FSIS of the shipment of adulterated or ineligible product. There have been no recalls of pork products exported from Finland since the previous FSIS audit conducted in 2021.

FFA implements Regulation (EU) 2017/625 as the basis for designation of an accredited laboratory. In order for a laboratory to be listed and designated by FFA as authorized to conduct official analysis of samples, the laboratory must first be accredited by the Finnish Accreditation Service (FINAS). FINAS accredits laboratories according to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. FFA receives FINAS audit results and reviews each specific method of analysis for which the laboratory has applied for approval. After review and evaluation, FFA lists the laboratory as a designated laboratory with the specific method that is approved for official analysis of samples. During the audit, the FSIS auditors verified through records review and interviews that laboratories performing analyses of officially required samples are accredited by FINAS and designated by FFA.

The FSIS auditors confirmed through record review that FINAS conducts yearly accreditation audits of the FFA National Reference Laboratory (NRL) to verify laboratories meet ISO/IEC 17025 standards. The FSIS auditors interviewed staff and reviewed documents from the NRL to verify implementation of procedures that ensure 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 auditors also reviewed internal employee training, proficiency testing requirements and results, and results of the most recent FINAS and internal FFA audits of the laboratory.

The FSIS auditors confirmed through record reviews that the Atria Suomi Oy Laboratory is accredited by FINAS to ISO/IEC 17025 standards and that FINAS conducts annual audits of the laboratory in support of the accreditation. The FSIS auditors verified the laboratory follows the *Salmonella* method that meets requirements of FFA, and all results of analysis for *Salmonella* are reported through the FFA reporting system. The FSIS auditors 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. The laboratory also maintains and implements procedures for calibrating equipment, internal employee training programs, and proficiency testing requirements for the analyses performed. The laboratory's analytical method currently in use for *Salmonella* testing and approved by FFA is consistent with ISO 6579-1:2017 and includes positive controls for every analysis performed.

The FSIS audit verification activities indicate that Finland's raw pork products inspection system is organized and administered by the national government, and that FFA inspection officials are assigned to enforce the laws and regulations governing raw pork products, providing ultimate control, supervision, and enforcement of regulatory requirements.

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 auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of 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 auditors 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 Finnish regulations and must take place within 24 hours of an animal's arrival at a slaughterhouse, and less than 24 hours prior to slaughter. During the performance of ante-mortem, the OV determines if the health or welfare of the animal is compromised and identifies any abnormality or disease condition which may affect the suitability of the animal for human consumption or any indication of use of prohibited or unauthorized substances. The OV also reviews food chain information of the animals being inspected, including health status of the animal, any prior veterinary treatments and associated withdrawal periods, and production data that may provide information on disease status of the animals. The OV also reviews the region of origin of the animal to ensure all APHIS animal health requirements are met. Any injured or non-ambulatory animal is identified, segregated and handled as distinctly separate from all other animals and clearly identified as not eligible for export to the United States through the entire process.

Finland ensures EU and FFA regulations are met regarding animal protections during transport and slaughter, including verification of humane handling, from the initial starting point of moving animals from the farm through the entire slaughter process. 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. The FSIS auditors verified through observations and record reviews that OVs 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. OVs document results of their verification procedures, including any administrative or enforcement actions they take based on an observation of noncompliance.

The FSIS auditors verified through interviews and record reviews that post-mortem inspection of each swine carcass, head and viscera occurs according to FFA Guideline 18511/8. Under supervision of OVs, the OAs perform inspection of every carcass and its parts 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. OAs identify carcasses and parts with signs of disease for further inspection and disposition by an OV on a side rail. Carcasses on the side rail cannot re-enter the production flow until an OV permits release of each carcass.

FFA Guideline 18510/8, 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 of condemned products and for implementing controls to ensure that such materials are clearly marked during operations and transported with the appropriate documentation to approved handling facilities. FSIS auditors verified through observation and record reviews that OVs verify establishment controls of material handling as part of their daily inspection verification procedures, and document results in Oiva.

An FFA regional manager conducts 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 OVs and OAs under the direct supervision of the supervisory OV. FFA senior officers from the Export Division also evaluate performance of the supervisory OV, OVs, MVO's and OAs during audits. The regional manager 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 personnel. Any observations of noncompliance are also documented, requiring a written response from the certified establishment with corrective actions. OVs 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 auditors verified supervisory activities through direct observation and review of records of the control visits and audit reports.

The FSIS auditors verified through observations and record reviews that FFA requires certified establishments to properly label products. Certified establishments are required to provide labels to OVs 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 permitted use on finished product by a certified establishment.

The FSIS audit activities indicate that FFA 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 auditors reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitary performance standards (SPS) and sanitary dressing.

The FSIS auditors verified through observation and record reviews that FFA requires certified establishments to comply with requirements of SPS and Sanitation SOPs in accordance with FFA Guideline 18510/8. The guideline requires establishments to develop, implement, monitor,

document results, and maintain written programs effective in ensuring all operations, including 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. The FSIS auditors verified that certified establishments maintain daily Sanitation SOP records of implementation, monitoring, and corrective actions in accordance with FFA requirements.

FFA Guideline 18511/8 requires regulatory oversight of the establishment's SPS and Sanitation SOP programs on a daily basis by the in-plant OVs. The FSIS auditors verified the adequacy of FFA verification activities by observing the OVs conducting pre-operational sanitation in one of the audited slaughter establishments. Pre-operational inspection is performed by the OV who either observes 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 FSIS auditors also verified that the OV documents the results of the verifications on their weekly control records with observations of any noncompliance documented in accordance with FFA guidelines.

FFA Guideline 18510/8 requires certified establishments to perform slaughter under hygienic conditions and FFA Guideline 18511/8 requires OVs to perform slaughter hygiene inspections to verify establishments maintain hygienic conditions. The FSIS auditors verified through observations and review of records that 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. The FSIS auditors verified certified establishments have written programs and maintain daily records sufficient to document implementation of sanitary dressing procedures.

The FSIS auditors verified through observation and interviews that FFA requires OVs to ensure certified establishments meet zero tolerance requirements for fecal material, ingesta and milk as required by FFA Guideline 18510/8. OVs perform zero tolerance checks to verify process control and document results on the weekly control record. OAs perform inspection of each carcass for fecal material, ingesta, and milk during post-mortem inspection. Any carcass with contamination is required to be trimmed immediately or sent to the side rail for trimming with subsequent reinspection of each carcass by FFA prior to movement back onto the production line.

The FSIS audit activities indicate that FFA requires certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs, 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 auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditors 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 18510/8. 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. The FSIS auditors verified the audit results during site visits to certified slaughter and processing establishments.

The OV verifies HACCP requirements are met by each certified establishment according to FFA Guideline 18511/8. The FSIS auditors 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 guidelines provides further instruction for how OVs 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 the results of verification checks on their weekly control form and includes noncompliances according to FFA guidelines.

The FSIS auditors observed and reviewed records documenting that OVs verify all CCPs according to the control plan developed at each certified establishment. OVs conduct zero tolerance checks to verify process control and verify establishment CCPs by either review of records or direct observation of establishment CCP monitoring. The FSIS auditors verified that if findings are observed, the OV 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 according to FFA guidelines. The OV would then review the establishment's corrective actions and written responses to ensure all HACCP requirements were satisfactorily met in accordance with FFA requirements.

The FSIS audit activities indicate that FFA requires 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 auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized, and administered by the national government, which includes random

sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

The FSIS auditors verified that Finland's National Residue Control Plan (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 and the Meat Control Unit are responsible for annual planning, implementation, and coordination of the NRCP in accordance with Commission Delegated Regulation (EU) 2022/1644 supplementing Regulation (EU) 2017/625, Commission Implementing Regulation (EU) 2022/1646, Commission Regulation (EU) 2023/915, Commission Delegated Regulation (EU) 2022/931 supplementing Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2022/932. The annual 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 annually to the supervisory OV in each certified establishment based upon the NRCP.

The FSIS auditors verified that OVs receive sample schedules from FFA annually with the specific details for every sample to be submitted on a monthly schedule. The OV randomly determines when each sample will be taken throughout each month. Samples are collected and packaged either by OVs or by OAs that are under direct supervision of OVs. Packaged samples include official forms describing the requested analysis, are sealed with a numbered FFA seal, and are shipped immediately under temperature-controlled conditions to the NRL for analysis. The FSIS auditors verified 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 auditors 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 Chemical Control Unit to then determine if a residue sample result is detected at a level that is violative of EU or U.S. tolerances, as described in FFA Guideline 18511/8, which requires review of both U.S. and EU tolerance levels for chemical residues.

The FSIS auditors verified that 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, the 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 audit activities indicate that FFA has overall authority of a chemical residue testing program designed and implemented to prevent and control the presence of veterinary drugs and

other chemical contaminants in pork products intended for export to the United States. 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 auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that pork products prepared for export to the United States are safe and wholesome.

FFA requires certified establishments to follow Commission Regulation (EC) No. 2073/2005 regarding indicator organism testing of swine carcasses. Certified establishments are required to sample carcasses at one point in the process 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).[2] The FSIS auditors verified by observation and review of records that OVs review establishment test programs, observe establishment sampling, and review test results on a routine basis and verify any 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 requires FFA to develop an annual sampling plan for the control of *Salmonella* in slaughter facilities. FFA's 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 auditors verified through interviews and record reviews that each certified establishment receives an instruction letter from FFA indicating the number of each type of sample that the establishment is responsible for collecting and having analyzed for *Salmonella*. 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 a designated laboratory and authorized to perform required *Salmonella* and indicator organism testing. The authorized laboratory must immediately notify FFA of a positive test result and send the isolate to the NRL for further characterization. The OV is also notified of the positive test result, and at that time begins 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.

[2] FSIS continues to work with FFA to ensure that microbiological sampling and analysis programs for monitoring process control throughout slaughter and dressing operations equivalent to U.S. requirements in 9 CFR 310.18 are implemented at certified establishments that export product to the United States.

The FSIS audit verification activities indicate that FFA requires microbiological sampling and testing programs to ensure that pork 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 May 29, 2024, by videoconference with FFA. FSIS 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 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.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
HKScan Finland Ltd. Teollisuuskatu 17 FORSSA	05/17/2024	18	Finland
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

45. During the site visit at Est. 18, the auditors observed areas of what appeared to be green algae like buildup on the lower edges of the plexi-glass cover at the exit of the controlled atmosphere stunner. The non-contact surfaces of the structure were not maintained in a sanitary manner.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/17/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Atria Ltd. Atriantie 1 60550 NURMO	05/21/2024	22	Finland
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

10. During the site visit to Est. 22, while observing pre-operational inspection the auditors identified product tubs were left in the cutting department from the previous day's production and were in the room during the cleaning and sanitizing process. Some of the tubs identified had small particles of product residue from the previous day's production and an accumulation of liquid from overspray of the cleaning and sanitizing process. As observed by the FSIS auditors, this is a deviation from the required process as the tubs are not permitted to be in or come into the room using the automated system until completion of pre-operational inspection. The establishment monitor and inspection personnel did not identify the deviation during their pre-operational inspection process.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/21/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pakastamo Ltd/HKScan Ltd Teollisuuskato 17 FORSSA	05/17/2024	S061101	Finland
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

No findings.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/17/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
HahkaWay Ltd. / Botnia Freeze Ltd. Keksijantie 2 Seinajoki	05/20/2024	S743109	Finland
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

No findings.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/20/2024

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

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2024

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 02.10.2024

Dnro/Dnr/DNo 6453/00.01.03.01.04/2023

Margaret Burns Rath, JD, MPH
Acting International Coordination Executive

Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, D.C. 20250
USA

ANSWER TO THE FOOD SAFETY AND INSPECTION SERVICE'S (FSIS) DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN FINLAND FROM MAY 15 THROUGH MAY 29, 2024

The Finnish Food Authority (FFA) wants to thank the FSIS for its draft final report of the routine equivalence verification audit conducted in Finland from May 15 through May 29, 2024. We have now thoroughly reviewed this draft final audit report, and in this letter, we would like to inform the FSIS of corrective actions taken to address the FSIS audit findings and give some technical comments regarding the information in the draft final audit report.

General corrective actions

The local official inspection personnel at each audited establishment wrote an inspection report to the establishment concerned, after the audit. In these reports the findings of the audit were listed, and the establishments were required to correct the findings, if it had not already been corrected during the audit. The senior specialist of FFA Export Section who participated in the audit also wrote an audit report to local official inspection personnel at each audited establishment. In this report FFA evaluated the functioning of the local official control of the establishment.

During September 2024, the senior specialist of FFA Export Section conducted regular audits to both US export approved slaughterhouses/cutting plants. During these audits the audit findings by FSIS of the concerned establishments were discussed in more detail. Corrections to the FSIS audit findings were verified during these audits and will be continued to be verified during subsequent regular audits by the FFA senior specialist.

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2024

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 02.10.2024
Dnro/Dnr/DNo 6453/00.01.03.01.04/2023

Sanitation Standard Operating Procedures (SSOP) Requirements/Enforcement

In the establishment check lists, that are attached to the draft final audit report, it is mentioned that in one of the establishments there was an observation during the pre-operational inspection. Product tubs had been left in the cutting department from the previous day's production and were in the room during the cleaning and sanitizing process. Some of the tubs also had small particles of product residue and an accumulation of liquid from overspray of the cleaning and sanitizing process. This was considered a deviation from the required process, as the tubs are not permitted to be in or come into the room until completion of pre-operational inspection. The establishment monitor and inspection personnel did not identify the deviation during their pre-operational inspection process.

Immediately during the audit, the tubs were removed from the cutting department and directed to be cleaned by the establishment personnel. The official veterinarians (OVs) at the establishment wrote a noncompliance report of the deficiency, and the establishment provided a written response to the report in the given deadline. As pre-emptive measures, the cutting room personnel will make sure that the conveyor belt from the tub cleaning room will be shut down each day after production, so no tubs come into the cutting department. If any tubs are identified in the cutting department before the start of cleaning, the cleaning personnel will remove them before starting the cleaning process. The cutting room personnel of the establishment will ensure the cleanliness of the tubs before using them. Checking the cleanliness of the tubs is also a part of the operational sanitation procedures conducted in the cutting department. If any tubs are identified in the cutting department during the pre-operational inspection, they will be removed before starting of operations. The subject is verified by the OVs at the establishment and during the regular audits conducted by the senior specialist of FFA Export Section.

Other observations: Equipment and Utensils/Enforcement

In the establishment check lists, that are attached to the draft final audit report, it is mentioned that in one of the establishments there was an observation of areas of what appeared to be green algae like buildup on the lower edges of the plexi-glass cover at the exit of the controlled atmosphere stunner. It was observed that the non-contact surfaces of the structure were not maintained in a sanitary manner.

The plexi-glass cover at the exit of the controlled atmosphere stunner was replaced by the establishment personnel immediately after the audit. This was verified by the establishment OVs and also by the senior specialist of FFA Export Section during the regular audit to the

establishment. It was concluded that the reason for the green algae like buildup was in the fastening of the plexi-glass cover; it was fastened in such a manner that small cavities formulated on the edges of the plexi-glass, which created an opportunity for buildup. After fastening of the new plexi-glass cover, the edges were filled out so that no such cavities are present. The establishment has an own-control plan for the cleaning of the plexi-glass cover, and this plan was also verified during the regular audit by the senior specialist of FFA Export Section.

Technical comments regarding the information in the Draft Final Audit Report

On page 5 it is mentioned that FFA senior specialists perform a follow-up review to verify corrective actions were implemented and effective in the establishment, in case any findings were made during a regular audit to the establishment. To clarify, these corrective measures and their effectiveness are reviewed during the following regular audits by the FFA senior specialists.

On page 5 it is mentioned that OVs are continuously present each day during slaughter and cutting operations. To clarify, the OVs are present continuously during slaughter operations, and verify establishment activities at least once per shift in the cutting plant as described in FFA Guideline 18511/8 *Official control of meat establishments approved to export to the U.S.*

On page 7 it is mentioned that ante-mortem inspection is carried out according to EU and FFA regulations, and also that Finland ensures EU and FFA regulations are met regarding animal protections during transport. In fact, the FFA does not have regulations, and thus a more correct term would be “Finnish regulations”.

On page 8 it is mentioned that an FFA regional manager conducts control visits on a quarterly basis, providing oversight and guidance to the supervisory OV in each certified establishment. It is also mentioned that 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 OVs and OAs under the direct supervision of the supervisory OV. We wish to clarify that the audits conducted by the FFA senior specialists of Export Section, and the supervisory visits conducted by the FFA regional managers of Meat Inspection Unit differ from each other. The regional managers of Meat Inspection Unit conduct regular supervisory visits to slaughterhouses according to an annual plan, supervising the meat inspection personnel at FFA controlled meat establishments. The regional managers’ visits focus on staff support and HR-style aspects and also on mentoring and advising staff on meat inspection and official controls matters. The regional manager of

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2024

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 02.10.2024
Dnro/Dnr/DNo 6453/00.01.03.01.04/2023

Meat Inspection Unit does not always document the supervisory visit, depending on the aspect of the visit. The FFA senior specialists of Export Section conduct audits to each certified slaughterhouse/cutting plant four times per year, evaluating the establishments compliance with US export requirements. The senior specialists of Export Section write a report of the results of each audit conducted in the US certified establishments.

On page 11 it is mentioned that FFA's Food Safety Department, Chemical Food Safety Unit is responsible for annual planning, implementation, and coordination of the NRCP. In fact, the Chemical Food Safety Unit and Meat Control Unit together are responsible for planning, implementation and co-ordination of the control programs.

In the establishment check lists, that are attached to the draft final audit report, the address for Atria Ltd. is incorrect. Instead of Lapuantie 594, Nurmo, the correct address for Atria Ltd. is Atriantie 1, 60550 Nurmo. Also, the name of the establishment Pakastamo Ltd./HK Ruokatalo Ltd. on the check list should be Pakastamo Ltd./HKScan Finland Ltd. (from September 2nd, 2024, the name is HKFoods Finland Oy).

Deputy Director-General of Food Chain Division Marjatta Rahkio

Senior Specialist Outi Renkonen
Export Section, Microbiological Food Safety Unit

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Tämä asiakirja on laadittu ja allekirjoitettu sähköisesti.
Dokumentet har satts upp och undertecknats elektroniskt.
This document has been digitally prepared and signed.

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Puh. 029 530 0400 (vaihde)
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