USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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SEP 0 3 2019

Dr. Taina Aaltonen
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PL 30
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Dear Dr. Aaltonen,

The United States Department of Agriculture, Food Safety and Inspection Service (FSIS) conducted an on-site equivalence verification audit from February 5 through February 8, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of Finland are included as an attachment to the report.

If you have any questions, please contact the Office of International Coordination by email at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN FINLAND

FEBRUARY 5-8, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 10, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from February 5-8, 2019. The purpose of the audit was to determine whether Finland's food safety 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 only raw pork 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings did not identify any deficiencies which represented an immediate threat to public health. The FSIS auditor identified the following findings:

Government Oversight

- 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.

Government HACCP System

- 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.

During the audit exit meeting, the CCA committed to addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions based on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Finland's food safety system from February 5-8, 2019. The audit began with an entrance meeting held on February 5, 2019, in Helsinki, Finland, during which time the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The Finnish Food Authority (FFA).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing raw pork products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The scope of this audit included all aspects of Finland's inspection system for producing and exporting raw meat products to the United States. Finland is currently eligible to export the following products to the United States:

Process Category	Product Category	Eligible Products
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product
Raw Product - Intact	Raw intact pork	Pork - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes that pork imported from Finland is considered free of Swine Vesicular Disease (SVD), free of Rinderpest and Foot and Mouth disease with restrictions, and free or at low risk of Classical Swine Fever (CSF). However, because of the detection of African Swine Fever (ASF) in domestic or feral swine in restricted zones established by the European Union (EU), special restrictions apply to Finland.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period in addition to information obtained directly from the CCA through the Self-Reporting Tool (SRT).

Representatives from the CCA and local inspection offices accompanied the FSIS auditor throughout the audit. 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at the CCA headquarters and at three local inspection offices. The FSIS auditor evaluated the implementation of control systems in place which ensure that the national system of inspection, verification, and enforcement is being implemented as intended. A sample of three establishments was selected from a total of four establishments certified to export raw pork product to the United States.

During the establishment visits, attention was paid to the extent to which industry and government interact to control hazards and prevent noncompliance issues that threaten food safety. The FSIS auditor assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, FSIS audited one microbiological laboratory and one residue laboratory to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Finnish Food Authority (FFA), Helsinki
Laboratories		2	• HKScan Finland Ltd., private microbiological laboratory, Vantaa • The Chemistry and Toxicology Unit, government residue laboratory, Helsinki
Pork slaughter and raw processing establishments		2	• Establishment 18, Forssa • Establishment 22, Nurmo
Cold storage facility		1	• Establishment S061101, Forssa

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); 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*; and includes the following:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;

- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC;
- Council Directive 96/23/EC; and
- Council Directive 97/747/EC.

III. BACKGROUND

From December 1, 2015, to November 30, 2018, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 2,926,493 pounds of raw pork products exported by Finland to the United States. FSIS also performed re-inspection on 429,801 pounds at POE for additional types of inspection (TOI), none of which were rejected for food safety-related reasons.

The previous FSIS audit in 2017 identified the following findings under the Government Oversight component.

- Inadequate government oversight of private microbiological laboratories performing food safety testing of product eligible for export to the United States, resulting in multiple deficiencies with the laboratories' implementation of internal quality control procedures were noted.
- Inadequate verification of government sanitation requirements to ensure that the establishment's corrective actions were effective to prevent the recurrence of noncompliance related to product contact surfaces.

The FSIS auditor determined that the CCA's corrective actions in response to the prior findings were implemented and effective.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Finland's SRT responses and supporting documentation. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations 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. The FSIS final audit report for Finland's food safety system is available on the FSIS website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that 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.

Finland, as a member of the European Union (EU), draws its authority to enforce inspection laws from *Regulation (EC) No. 178/2002 of the European Parliament and of the Council,* dated January 28, 2002. The regulation establishes the general principles and requirements of food law and defines European Food Safety Authority and procedures in matters of food safety. The EU regulations are the primary overarching laws for regulating meat inspection. Finland is responsible for ensuring that adulterated or misbranded products are not exported to the United States through its national legislation and implemented regulations. Additional authority to enact European and national legislation are grounded in the *Finnish Food Act 23/2006 including amendments through 352/2011* and *Meat Inspection Decree 590/2014.* The CCA is responsible for directing, planning, steering, and carrying out food safety and animal health and welfare controls.

The FSIS auditor verified that the inspection system is organized and administered by the national government of Finland at three distinct levels with the CCA at the central level, headquartered at Helsinki. The other two levels operate at regional and local (municipal) levels. Through an official correspondence received on November 21, 2018, by FSIS' Office of International Coordination, the Agency learned that the Finnish Food Safety Authority (EVIRA) was undergoing a reorganization effective January 1, 2019. Beginning January 1, 2019, EVIRA will be known as "The Finnish Food Authority (FFA)".

The FSIS auditor conducted interviews with the CCA's representatives and reviewed documents at the central and local inspection offices. The FSIS auditor gathered information related to changes from the reorganization that occurred at the CCA level and assessed the impact of the reorganization on both the food inspection system and on the ability to maintain food safety and inspection systems equivalent to those in the United States.

The Finnish Food Authority (FFA) was formed as a result of the integration of EVIRA, the Rural Affairs Agency, and part of the Information Technology Services of the National Land Survey of Finland into one consolidated entity. FFA became operative on January 1, 2019, while remaining under the oversight of the Ministry of Agriculture and Forestry (MAF) and is now headquartered in Seinajoki. The activities of FFA stretch across Finland with the help of a work force consisting of roughly 1,000 employees supporting FFA's mission of food safety, rural development, research, and administrative tasks. FFA is headed by the Director General (DG), who is supported by a team of advisors and the internal audit unit. The DG of FFA directly

reports to MAF on matters of food safety and oversees the EU coordination and international affairs.

FFA is comprised of three main divisions and their respective departments, units, and sections. The three divisions are the Rural Areas Division (RAD), the Laboratory and Research Division (LRD), and the Food Chain Division (FCD). The RAD is involved chiefly with rural development programs and managing funds and monitoring the distribution of subsidies as planned. The LRD is responsible for matters related to animal and plant disease and diagnostics, laboratory studies related to food, feeds, fertilizers, and plant protection products including plants, and for taking the lead in developing risk assessment procedures. The laboratory conducts analysis on samples requiring monitoring, oversight, and acts as a reference laboratory. The LRD also conducts scientific research and maintains the necessary national research infrastructure in Finland.

Among the three divisions described, it is the FCD which is responsible for safety of all foods including foods of animal origin, meat inspection, and export. The organizational structure within the FCD comprises the Food Safety Department, which then subdivides into the following three units, the Microbiological Food Safety Unit (MFSU), the Chemical Food Safety Unit (CFSU), and the Meat Inspection Unit (MIU). Each unit is further split into function-specific sections; for example, the MFSU is specifically responsible for matters related to export of meat to the United States and other importing countries. The CFSU has sections dealing with food composition, organic foods, and feed. The MIU further branches into three sections overseeing the inspection activities in Southern, Central, and Northern Finland.

The FSIS auditor confirmed that the MFSU issues guidelines and instructions to its inspection personnel that deal with the frequency of supervisory reviews and the procedures for registration, approval, and withdrawal of approval of the United States eligible establishments. The *Finnish Food Act 23/2006 (and its amendments)*, *Section 61*, outlines the procedures for *"Cancelling the Approval of Food Premises*" by the CCA. Establishments failing to correct noncompliance related to HACCP, sanitation standard operating procedures (sanitation SOP) or issues impacting food safety may receive a warning letter, a Notice of Intent to Delist (NOID), or cancellation based on the extent of the noncompliance, public health significance, and the establishment's compliance history. If an establishment is given more than three warning letters during a period of two years, then the establishment's export approval is removed.

The MFSU is also responsible for verification of the microbiological sampling, the performance of official inspection tasks, and the scope and method of carrying out the National Residue Control Program (NRCP) in accordance with *EC Directives 96/22* and *96/23*. The FSIS auditor reviewed the NRCP. The program did not reference the holding of carcasses or parts when samples are taken for routine chemical analysis. The FSIS auditor identified the following finding:

- The 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.

At the audited establishments, the FSIS auditor assessed the Finnish verification procedures that ensures that source meat products used in processing operations for export to the United States originate only from certified establishments in accordance with EU regulations and *Guideline 18510/3 - Requirements for meat establishments approved to export to the US.* The document reviews provided evidence that only pork products originating from animals slaughtered at certified establishments are shipped to the United States.

The FSIS auditor verified that official inspection personnel are employees of the Finnish government at all levels of Finland's inspection system. The CCA is responsible for hiring and assigning qualified inspection personnel, based on *Statute No. 38/EE/2006*, to perform inspection and enforcement activities at the certified establishments. FFA is funded by the national government, whose revenue includes fees assessed to meat establishments as provided under the authority of the *Finnish Food Act 23/2006 (and its amendments)*, *Chapter 8*, which outlines the criteria for charges for services carried out by government authorities.

The FSIS auditor verified that FFA ensures that inspection personnel have appropriate education credentials and necessary training and experience to carry out inspection tasks. FFA requires that a veterinary medical officer must have a Doctor of Veterinary Medicine or equivalent degree. In Finland, veterinarians take meat inspection courses in the curriculum of their formal education. Official auxiliaries (OAs), in accordance with *Regulation (EC) No. 854/2004*, have inspection courses involving practical training on the slaughter line and theoretical classroom training, after which they must pass specific examinations before being qualified to work in export meat establishments.

The FSIS auditor verified that the CCA has implemented and conducted ongoing training programs intended to ensure that in-plant inspection personnel are aware of specific food safety and inspection requirements that pertain to Finland's meat export to the United States. The FSIS auditor verified that the CCA had delivered a training session on "Information on United States Export Requirements". The training was held on October 11, 2018, and attended by the inspection staff assigned to establishments eligible to export to the United States, and assigned to the export section personnel at the headquarters. Among the topics covered in the training was control of laboratories and findings of audits conducted by the CCA in the eligible establishments. The FSIS auditor verified the training records of official veterinarians (OV) and OAs in addition to observing in-plant inspection personnel while they were conducting their inspection activities, and the FSIS auditor concluded that the personnel have sufficient training to perform their duties.

The CCA has a system to approve laboratories interested in conducting analysis on official samples, including samples of products for the United States export. For a laboratory to be approved, it is required to have a documented quality control system in accordance with criteria laid out in the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories*. Additionally, the approved laboratories need to demonstrate that they are technically competent in producing reliable results. The laboratories must comply with the pertinent requirements stipulated in the *Food Act 23/2006* (and its amendments), *Feed Act 86/2008*, Fertilizer Act 539/2006, *Animal Diseases Act 441/2013*, *Health Protection Act*

763/1994 and *Animal By Product Act 517/2015*. Finland's NRCP is based on the EU and Finnish legislation. Coordination and communication occur between the Food Safety Steering Group and FFA to develop and implement the NRCP and microbial sampling plans to ensure that Finland meets United States requirements.

Finally, the FSIS auditor verified the implementation of corrective actions by the CCA in response to the 2017 audit findings. Through interviews with the CCA representatives and a review of documents during the microbiological laboratory audit, the FSIS auditor verified that the laboratory had developed procedures to monitor temperature of incubators during off-days or national holidays. The FSIS auditor also verified the updated standard operating procedure (SOP) document, which addresses the 2017 audit finding on the storage temperature of agar (laboratory culture medium) during storage. The updated SOP was written to ensure that technicians handling laboratory reagents and agar follow storage guidelines.

Additionally, the CCA had increased oversight activities in response to FSIS 2017 audit findings to ensure that the private laboratory was adhering to the updated SOPs. The FSIS auditor further verified records and documentation, during the current audit that all sanitation related findings from the 2017 audit were corrected and verified by the inspectors at the local level and by the supervisors at the central level. Since the 2017 audit, the CCA has updated two of its guidance documents: *Guideline 18510/3 Requirements for meat establishments approved to export to the US;* and *Manual 18511/3 Official control of meat establishments approved to export to the US.*

The FSIS auditor determined that Finland's government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at certified establishments. However, the CCA allows the issuance of export certificates for products intended for export to the United States even though chemical residue test results have not been confirmed negative prior to shipping to the United States.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that 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 parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The FSIS auditor observed that the inspection personnel at the two audited slaughter facilities were verifying the establishments' compliance with humane handling and slaughter. The dedicated ante-mortem OV or his designee are present during the unloading of animals and observe the humane hauling of the swine to the pens, the walkways leading to the stunning area,

and the stunning procedures to ensure animals are completely insensible by checking palpebral reflexes. The result of the verification is entered in the monitoring verification form maintained in the inspection office.

The FSIS auditor observed that pens are equipped with water troughs and that there are provisions for feeders for animals kept over 24 hours. Each audited facility had a pen marked as a suspect pen to keep sick or downed pigs separate from the healthy stock. The FSIS auditor determined that the verification procedures employed by the inspectors related to humane handling and humane slaughter were in accordance with applicable EU and Finnish legislation.

The FSIS auditor verified that inspection personnel reviewed the incoming registration and identification documents with each consignment of swine and observed all animals from both sides while at rest and in motion. Swine exhibiting signs of disease for any reasons are retained in the suspect pen with a separate pen card completed by the OV. Ante-mortem results for each lot is documented on the pen cards. The dedicated veterinarian or an OA under an OV's supervision follows instructions and guidance outlined in EU regulations and *Manual 18511/3* when conducting ante-mortem verification of pigs offered for slaughter. In Finland, only swine that originates in Finland is slaughtered at establishments that are eligible for export to the United States to ensure that only meat products that are currently not restricted by APHIS are designated for export to the United States.

The FSIS auditor observed OAs performing examination of swine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes under the supervision of an OV. The carcasses found with pathology are railed out along with associated viscera and parts for veterinary disposition. Inspection procedures applied to conduct post-mortem inspection were in accordance with EU regulations, which have been recognized as equivalent to FSIS requirements. The FSIS auditor further verified that inspection personnel ensuring that establishments apply procedures for proper presentation, identification, examination, and disposition of carcasses and parts. No concerns were identified with the ante-mortem and post-mortem inspection criteria.

The FSIS auditor reviewed a sample of government records concerning condemnation of swine during ante-mortem or post-mortem inspection. The records show that all inspectors use a condemnation form to document all such action. Product unsuitable for human food are treated with denaturant prior to their removal from the premises for rendering as required under *Statute No. 38/EEO/2006*.

The FSIS auditor verified that at each slaughter establishment only government-assigned inspectors provide continuous coverage at all shifts and conduct all official verification activities including ante-mortem and post-mortem inspection. Through interviews and record reviews at the two audited slaughter establishments, the FSIS auditor determined that Finland maintains inspection of every carcass and parts in all pork slaughter establishments. The FSIS auditor further verified that at least once per shift inspection is maintained at the cold storage establishment when a shipment destined for the United States needs verification and certification. The government inspection staff consists of team of veterinarians and auxiliaries

led by a supervisory official veterinarian (SOV) who oversees the implementation and enforces inspection requirements at the certified establishments.

To verify if the CCA is meeting the requirements of 9 CFR Part 327.2, related to periodic supervisory visits at the certified establishments, the FSIS auditor reviewed the recent reports generated by the senior officer (SO) of the Export Section in FFA. The SO conducts these reviews in accordance with *Guidelines 18510/3* and *Manual 18511/3*. These documents provide guidance to FFA staff on the scope of government verification activities and the methods to be applied when verifying compliance with EU, national, and specifically FSIS requirements during supervisory reviews or by the SOV and his team when conducting routine inspection verification activities conducted at the certified establishments.

The supervisory reviews conducted by the SO are multifaceted plans consisting of a phase devoted to evaluation of the adequacy of establishments' food safety systems, a review of inspection documents, and a segment on requiring the observation of inspectors conducting verification activities. The establishment portion of the review encompasses all aspects of establishment food safety programs including sanitation, HACCP, *Salmonella* and *E. coli* sampling, and corrective actions establishments have taken to address any noncompliance. The frequency of these supervisory reviews is laid out in the annual audit plan, which is established at the central level at the end of each year for the next year. The review of recent supervisory reports indicates the supervisory visits are being carried with the planned frequencies with a focus on both establishment compliance and inspectors' performance. No concerns arose as a result of verification of the supervisory reviews.

The FSIS auditor verified that there is a separation of product eligible for export to the United States from product not meeting requirements. In-plant inspection personnel verify that operators comply with the requirements for separation of product destined for the United States. In-plant personnel verify requirements for separation of products and document results on the supervisory monitoring plan record (SMPR). The FSIS auditor verified the use of product codes with designated codes for export to the United States and segregation of final boxed product. The FSIS auditor verified that establishments maintain a written program to define separation of products destined for export to the United States.

The FSIS auditor concluded that the CCA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all the audited establishments. *Chapter 2.1* of *Guideline 18510/3* lays

out the requirements for maintenance of sanitary operation in the establishments eligible to export product to the United States. The establishment must develop and implement sanitation program that must include sanitation SOPs and sanitation performance standards (SPS) consistent with provisions contain in 9 CFR Part 416. Establishments are to define procedures for operational and pre-operational sanitation separately.

The FFA issued *Manual 18511/3,* which provides instructions to in-plant inspection personnel assigned to the certified establishments on how to verify sanitation requirements consistent with 9 CFR Part 416, which includes evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation, monitoring of sanitation procedures including hands-on verification, and records review. The supervisory monitoring plan developed at the central level contains a schedule of frequencies of verification tasks. These tasks are risk-based, and may vary from daily, weekly, monthly, or yearly based on whether the tasks to be performed are sanitation SOPs or SPS. As such, the frequencies of tasks for sanitation SOP verification is set as daily for inspection personnel to verify accordingly.

The FSIS auditor verified that the government-assigned inspectors conduct verification of sanitary conditions in accordance with the procedures outlined in *Manual 18511/3*. The FSIS auditor observed the sanitary dressing processes to verify implementation of practices for prevention of contamination during dressing procedures and viscera removal. The FSIS auditor also observed in-plant inspection personnel conducting verification of the establishment's sanitary dressing procedures of porcine carcass and parts.

In one of the two audited slaughter establishments, the FSIS auditor verified the actual pre-operational inspection by observing the in-plant inspector conducting pre-operational sanitation verification of processing areas. The OV's hands-on verification procedures began after the establishment personnel had conducted their pre-operational sanitation and determined that the facility was ready for in-plant inspector pre-operational sanitation verification activities. The OV documents the outcome of the pre-operational verification on the government-issued form and allows the establishment to proceed with cutting and slaughter operations. The FSIS auditor determined that the OV conducts this activity in accordance with the CCA's established procedures. The review of the establishment's monitoring records for operational and pre-operational sanitation indicates a comparability with those of inspectors' records with respect to sanitary conditions observed at the audited establishments.

The FSIS auditor verified that the CCA's corrective actions in response to the 2017 FSIS audit findings in the Government Oversight component were effective in resolving the issues. The FSIS auditor did not identify similar findings during this audit. The CCA's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

In Finland, food businesses including establishments slaughtering livestock are required to develop, implement, and maintain HACCP systems pursuant to provisions of *Article 5* of *Regulation (EC) No. 852/2004* and *Section 20* of the *Food Act 23/2006 (and its amendments)*. Additional requirements are contained in *Decree 795/2014* of MAF on the food hygiene at establishments (*Decree on Approved Establishments*). The decree specifically outlines the requirements on management of risks and establishment of critical points in the process.

To facilitate the correct implementation of HACCP requirements by the establishments eligible to export to the United States, FFA provided a guidance document titled "*Guideline 18510/3 Requirements for meat establishments approved to export to the US".* The "*Guideline 10002/2 On Implementing the HACCP Principles"* provides additional requirements to be implemented by the exporting pork slaughter establishments. These requirements are consistent with FSIS requirements cited in 9 CFR Part 417 for the implementation of HACCP. For the guidance of inspectors to apply correct HACCP verification procedures at the United States eligible establishments, the CCA has published *Manual 18511/3 Official control of meat establishments approved to export to the US.*

At the two audited slaughter establishments, the FSIS auditor conducted an on-site review of the establishments' HACCP systems, including flow charts, hazard analyses, HACCP plans, and other HACCP-related monitoring and verification records. The establishments maintain all decision-making documents for monitoring and verification frequencies. The review of monitoring and verification documents revealed that these activities are conducted in accordance with frequencies described in the above referenced document. Deviations from critical limits invokes a four-step corrective action plan consistent with the FSIS requirements in 9 CFR Part 417.3.

The FSIS auditor performed direct observation to verify government inspectors ensuring verification of HACCP systems being implemented in the audited establishments. The FSIS auditor conducted an on-site observation and reviewed the documentation of the zero tolerance controls of fecal material and ingesta. The presence of fecal material and ingesta is controlled through a critical control point (CCP). The FSIS auditor also verified the physical CCP location by observing the OV conducting HACCP hands-on verification activities. The FSIS auditor identified the following finding:

- 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 review of slaughter records at both audited establishments provide evidence that the market hogs are the preponderant class of pigs slaughtered; however, establishments may slaughter sows or boars if offered for slaughter. There was no observation of milk on pork carcasses and parts by the FSIS auditor, or the government inspectors during the audit. The FSIS auditor reviewed the in-plant inspection HACCP verification records and associated CCPs. Without the

requirement to ensure zero tolerance of milk on pork carcasses and parts, there were no records to identify if deviations occurred. These records are maintained on the electronic SMPR in addition to hard copies kept in the inspection office. The review of the establishments' corrective actions in response to any deviation from critical limits indicated that the establishments' corrective actions were adequately documented and verified by FFA's personnel as meeting all HACCP corrective actions consistent with FSIS requirements in 9 CFR Part 417.3(a).

The FSIS auditor's review of documents related to the hazard analysis, HACCP plans, monitoring, verification, and corrective actions as well as on-site observation of the inspection personnel conducting inspection and documenting results, revealed that the CCA requires establishments certified to export to the United States to develop and implement a HACCP system. However, the CCA did not include written provisions to ensure zero tolerance of milk on pork carcasses and parts.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts reviewed Finland's NRCP for 2018, associated methods of analysis, and additional SRT responses outlining the structure of Finland's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit in 2017.

The verification of this component consisted of interviews conducted at all audit locations, document reviews, and an audit of a chemical residue laboratory. FSIS based its verification of Finland's chemical residue testing program on information contained in Finland's Annual Residue Control Plan for 2018, which included 2017 testing results. Finland's NRCP is based on EU directives (*Council Directive 96/23/EC of 29 April 1996, Council Directive 96/22/EC of 29 April 1996)*, and *Regulation (EC) No. 470/2009/EU On procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.*

National legislation to control chemical contaminants in food of animal origin include: the *Finnish Food Act 23/2006 (and its amendments),* the *Act on Medication of Animals 387/2014,* and the *Decree of Ministry of Agriculture and Forestry on Residues in Foodstuffs of Animal Origin 1/EEO/2007*. These documents confer the legal authority upon the CCA to plan, regulate, and execute activities of the inspection system to ensure the prevention and control of the presence of residues of veterinary drugs and other contaminants in the tissues of swine slaughtered for meat and meat products for human consumption. Further, these documents delineate the conditions of chemicals use in the production of meat and animal feed. Finally, Finland draws its authority through the aforementioned acts and the decree issued by MAF to

prohibit the use of compounds injurious to public health and the ability to control and monitor industrial and environmental contaminants entering human foods, including meat of animal origin.

Development of the annual residue plan is a collaborative effort between the National Residue Reference Laboratory - The Chemistry and Toxicology Research Unit, the Food and Feed Microbiology Research Unit, and the Risk Assessment Unit of the Research and Laboratory Department of FFA. The annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the tolerance level of the residues, and the total number of samples to be collected; in this case, FSIS' concern is swine since it is the only species of export to the United States.

The implementation of the NRCP spans three testing locations that include testing of live animals at the farms, food businesses operating within municipalities, and slaughter establishments. The Regional State Administrative Agencies have authority over testing at farms on live animals, while sampling at the municipal level is overseen by Municipal Food Control Authorities. Samples drawn under the NRCP in municipalities may include non-meat matrices like milk or eggs.

The FSIS auditor verified implementation of the NRCP at the audited establishments. FFA provides instructions and sampling plans to inspection personnel responsible for collecting samples for residue analyses. At one establishment, the inspection personnel simulated the sample collection and packing and shipping procedures for the FSIS auditor. The sample collection occurs as an OV randomly selects the carcass to sample, completes the laboratory submission form, encloses a copy of the form in the sample shipment cooler, and then secures the shipment with a numbered seal to maintain the sample integrity. Following the review of inspection records and the interviews conducted with the inspectors, the FSIS auditor concluded that government inspectors subject all suspect animals or animals exhibiting pathological signs including injection sites to compulsory testing. Carcasses and parts under inspector-initiated testing are always retained until negative test results are obtained.

FSIS' review of documentation at the two audited local inspection offices indicated that in-plant government inspection personnel sample the required matrices for detection of specific analytes. The review of sampling records further revealed that the testing for the current year was on schedule in accordance with the collection schedule plan. FSIS' review of the monitoring results for 2018 indicates that no violative samples were detected.

The FSIS auditor visited the Chemistry and Toxicology Research Unit of the government-owned and operated laboratory in Helsinki. The laboratory is a National Reference Laboratory for all commodities and all substance groups listed in *Annex 1* of *Council Directive 96/23/EC.* The FSIS auditor interviewed the management personnel who oversee the laboratory's quality management system and the testing and analyses conducted under Finland's NRCP. The FSIS auditor reviewed SOPs for sample handling; sampling frequency; timely analysis; data reporting; analytical methodologies; tissue matrices; equipment operation; detection levels; percent

recoveries; intra-laboratory check samples; and quality assurance programs, including corrective actions and analysts' training records.

The FSIS auditor reviewed the recent internal and external audit reports. The Finnish Accreditation Service (FINAS), an accreditation body in Finland, audited the laboratory from October 9-24, 2018. FINAS' audit scope was comprehensive and encompassed among others equipment calibration and analytical methods. The accreditation audit identified some noncompliance related to ISO 17025 requirements, which were corrected, and a written report of corrective actions was submitted to FINAS. The FSIS auditor followed up on the implementation of corrective actions to the FINAS accreditation audit through document review and during the tour of the laboratory and concluded the laboratory had complied with ISO 17025 standards. The next FINAS audit of the laboratory is scheduled for October 19, 2019. The FSIS auditor's review of laboratory documents, interviews of analysts, and the site visit of the laboratory did not raise any concerns.

The FSIS auditor verified that FFA has implemented the NRCP in accordance with EU regulations. FFA has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols. The program contains provisions that ensure any product with residues exceeding established tolerances, if applicable, is condemned and ineligible for use as human food. The FSIS auditor determined that Finland's pork inspection system continues to maintain equivalent regulatory requirements for their chemical residue testing program that meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

Finland requires all slaughter establishments to develop and implement sampling and testing programs for the indicators of fecal contamination to assess the effectiveness of their slaughter and dressing process control procedures during the production of raw meat. To achieve the requirements of testing for indicators of fecal contamination, the CCA has given the option to establishments either to implement provisions contained in *Regulation (EC) No. 2073/2005 of November 15, 2005, on Microbiological Criteria for Foodstuffs* if testing for *Enterobacteriaceae* or follow the provisions consistent with 9 CFR Part 310.25(a) if testing for generic *E. coli.*

The FSIS auditor verified through document reviews and direct observation that one of the audited slaughter and processing establishments was testing for *Enterobacteriaceae* in accordance with *Regulation (EC) No. 2073/2005,* which also require testing for aerobic colony count (ACC). The other audited establishment had implemented a generic *E. coli* testing program to verify process control of livestock carcasses in accordance with 9 CFR Part 310.25(a). For both *Enterobacteriaceae* and ACC, five carcasses are sampled randomly on each sampling day using destructive methods from four points on the carcass in accordance with ISO

17604 standards. Samples are analyzed in accredited laboratories using the Nordic Committee on Food Analysis (NMKL) 144:2005 test method for *Enterobacteriaceae* and Association of Official Agricultural Chemists (AOAC) Official Method Petrifilm 3M for ACC. The samples for generic *E. coli* analysis are conducted in accredited private microbiology laboratories using AOAC approved NMKL method or AOAC Petrifilm 3M method. *Annex 9* of *Manual 18511/3* and *Section 2.5* of *Guideline 18510/3* describe generic *E. coli* requirements per 9 CFR Part 310.25(a). The FSIS auditor's review of the establishments' *Enterobacteriaceae*, ACC and generic *E. coli* testing programs, related records, and the review of test results did not identify any concerns.

Regarding official verification activities, the OVs in each eligible slaughter and processing establishment verify at least one of the tasks listed in Attachment 3 of *Manual 18511/3* related to sampling, approved analytical method, review of results and statistical process control chart to confirm that slaughter process control remains within established limits. The guidance document referenced above provides instructions for the OV, which includes direct observation of at least 10 percent of the sample collection when establishment employees are collecting samples. Additionally, the compliance with the testing requirements of generic *E. coli* or other indicators of fecal contamination and the performance of inspector's verification are also assessed once every year in each eligible slaughter establishment at the central level through an audit by an SO from FFA. The FSIS auditor determined that the instructions in the guidance document mentioned above are followed in the performance of verification of establishment testing procedures and analyses.

The *MAF Decree 134/2012 on Salmonella Control in Meat Establishments* regulates the national *Salmonella* reduction program. Under the program, *Salmonella* prevalence in market swine, sows, and boars are monitored at the national level. As part of the program, establishments slaughtering swine are required to collect ileocecal lymph nodes (LN) from a randomly selected carcass as well as swabs taken from carcass surfaces. The principal object of Finland's national *Salmonella* control program is to keep the prevalence of *Salmonella* in pork products and in living swine animals below one percent. The results of 2017 testing under the national *Salmonella* reduction program indicate that for each type of sampling (LN or carcass swabs) out of 3,000 samples collected from each product type (limited to sows and boars), less than 0.1 percent were positive for *Salmonella*. Test data for carcass swabs taken from all class of products did not yield any positive (detection) result. The result of testing for 2018 in two eligible slaughter establishments indicates that 2,515 and 478 samples were drawn from porcine carcasses and pork meat respectively yielding a zero percent failure. Based on the outcome of the testing program, the FSIS auditor concluded that Finland maintains its *Salmonella* prevalence rate well below the target of one percent.

For *Salmonella* testing of raw product, establishment employees collect the samples and private laboratories analyze them, which is determined to be equivalent by FSIS under the World Trade Organization's Sanitary/Phytosanitary Agreement. The FSIS auditor evaluated the implementation of the *Salmonella* testing program of the audited establishments. In Finland, *Salmonella* sampling requirements are consistent with 9 CFR Part 310.25(b), and *Guideline 18510/3*. The frequency of *Salmonella* sampling is set by the CCA. Sampling includes both carcasses swabs and collection of ileocecal LN for the detection of *Salmonella* spp. Sampling

occurs in all certified establishments that slaughter livestock. The FSIS auditor reviewed records, including results of *Salmonella* testing for the last year at both audited slaughter and processing establishments. The results showed no *Salmonella* set failures for the period reviewed. In one of the audited establishments, the FSIS auditor observed the in-plant personnel conducting verification activities while an establishment employee swabbed a porcine carcass using aseptic technique for *Salmonella* testing. The FSIS auditor did not identify any concerns.

In relation to analytical methods employed to analyze samples for *Salmonella* detection, the FSIS auditor verified a sample of certificate of analysis at two audited establishments. One establishment utilizes ISO 6579:2002/Amendment 1:2007 while the other establishment employs ISO 6579:2017. The CCA has given the option for alternative test methods to detect *Salmonella* in carcasses and meat. Regardless of the methods employed, if product tested positive for the presence of *Salmonella,* then laboratories need to confirm the result using Analytical Profile Index (API) 20E biochemical panel for identification. All positive samples are subject to the polymerase chain reaction (PCR) and ISO 6579-3:2014 testing methods at the FFA's laboratory for confirmation and serotyping steps respectively.

The FSIS auditor reviewed HKScan Finland Ltd., a private microbiological laboratory in Vantaa. The FSIS auditor reviewed the recent ISO 17025 accreditation audit report of the laboratory conducted by FINAS. The scope of the accreditation of this laboratory, which was issued on April 4, 2018, and expires on March 1, 2020, contains all microbiological analyses and methods necessary to support the CCA's verification testing for the certified establishment. The FINAS audit discovered that the laboratory was using an older version of the ISO method (ISO 6579:2002) for *Salmonella* testing even though the ISO had published a newer version of the method in 2017. The laboratory addressed the noncompliance by updating the method to ISO 6579:1:2017, *Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of Salmonella -- Part 1: Detection of Salmonella spp*. and provided the written corrective action to FINAS; the latter accepted the corrective actions applied by the laboratory. During the laboratory visit, the FSIS auditor also reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and checking of samples. In addition, the FSIS auditor reviewed training records and the results of proficiency testing and toured the relevant portion of the laboratory. There were no deficiencies identified during the review of documents.

The FSIS auditor verified that the CCA's corrective actions in response to the 2017 FSIS audit findings in the Government Oversight component were effective in resolving the issues. The CCA organizes and administers microbiological testing programs to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The CCA's meat inspection system continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on February 8, 2019, in Helsinki, Finland with FFA. At this meeting, the FSIS auditor presented the preliminary findings from the audit.

An analysis of the findings did not identify any deficiencies which represented an immediate threat to public health. The FSIS auditor identified the following findings:

Government Oversight

- The 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.

Government HACCP System

- The CCA has regulatory requirements for zero tolerance of feces and ingesta; however, there are no requirements for zero tolerance of milk on pork carcasses and parts.

During the audit exit meeting, the CCA committed to addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions based on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

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	02/05/2019	18	Finland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

15/51. In the establishment's hazard analysis the presence of milk on pork carcasses and parts was not considered a hazard reasonably likely to occur.

45/51. The establishment uses same color and shape containers for storing edible or inedible product with no label as to which was inedible. This practice creates a potential for comingling and product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/05/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Atria Ltd. Lapuantie 594 NURMO	02/06/2019	22	Finland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

15/51. The establishment identified presence of milk as hazard likely to occur in the hazard analysis, however, failed to identify measures to control the hazard in their HACCP plan, or SSOP or in any other prerequisite program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/06/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pakastamo Ltd/HK Ruokatalo Ltd Teollisuuskato 17 FORSSA Etelä-Suomen lääni (fi)	02/05/2019	S061101	Finland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment
No findings identified

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/05/2019

Appendix B: Foreign Country Response to Draft Final Audit Report

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2019

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 09.07.2019

Dnro/Dnr/DNo 678/00.01.03.01.04/2019

Dr. Michelle Catlin
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 (FSIS) DRAFT FINAL REPORT OF THE AUDIT CONDUCTED IN FINLAND FROM FEBRUARY 5 THROUGH FEBRUARY 8, 2019

Finnish Food Authority (FFA) has thoroughly reviewed the Food Safety and Inspection Service (FSIS) draft final audit report, concerning the on-site equivalence verification audit conducted in Finland by FSIS from February 5 through February 8, 2019. During the audit exit meeting FFA informed the FSIS auditor about the action plan set to follow up the preliminary findings of the audit. With the present letter FFA informs about the corrective actions taken by Finland to address the audit findings and gives 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. The senior officer at FFA in charge of exports of pork to the US, 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.

On March 19th, 2019 a meeting for all US export approved establishments and local official inspection personnel at these establishments was organized by FFA. The topics of the meeting were: general information of the FSIS audit, findings of the audit, corrective actions and

feedback for FFA for organizing future audits. The aim of the meeting was to make sure all establishments and local official inspection personnel would have the same and up-to-date information of the audit, the findings and actions required.

In April 2019, the senior officer at FFA conducted audits to all four US export approved establishments. During these audits the audit findings by FSIS of the concerned establishment were discussed in more detail. The corrections of the FSIS audit findings were also verified during these and subsequent routine audits by the senior officer. The establishments have also provided descriptions of corrective actions performed in writing to FFA.

Government Oversight: Routine Chemical Residue Program Results

The first finding mentioned in the draft final audit report, explains that FFA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the FFA's routine chemical residue program.

In Finland it is very rare to have violative findings in routine chemical residue samples. Residues of permitted medicines are very rarely detected, and the use of prohibited growth hormones has never been discovered. In case of a violative finding, it always leads to investigations, and when necessary immediate actions will be taken, and products will be recalled. By these means the Finnish food control system controls the potential hazards related to residues and secures consumer safety.

As the requirement of holding all routine sampled carcasses in exports to the US is new and affects export not only from Finland but also from other EU Member States, the European Commission has announced its intention to discuss the requirement with FSIS. The requirement is challenging as the residue control program has originally been developed to be a monitoring tool and not for the inspection of individual export consignments. We hope that the discussions between EU Commission and FSIS will further clarify the need and contents of the new requirement. In the meantime, the Finnish authorities consider various possibilities to meet this requirement and will implement corrective actions before the end of 2019.

For livestock carcasses and parts subjected to suspect chemical residue testing the carcasses and offal are always held by the official veterinarian pending the test results (Council Directive on Measures to Monitor Residues in Animals and Animal Products (96/23/EC), Ministry of Agriculture and Forestry Decree on Residues in Foodstuffs of Animal Origin (1/EEO/2007)).

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2019

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 09.07.2019

Dnro/Dnr/DNo 678/00.01.03.01.04/2019

Government HACCP System: Zero Tolerance Requirement for Milk

The second finding mentioned in the draft final audit report, explains that FFA has regulatory requirements for zero tolerance of feces and ingesta; but no written requirements for zero tolerance of milk on pork carcasses and parts.

In Finland only pigs, too young to produce milk, are slaughtered for export to the US. In carcasses from young pigs, contamination with milk has not been considered a common risk. However, after the FSIS audit FFA has updated the official guidelines on requirements for and control of meat establishments approved to export to the US, to include also zero tolerance requirements for milk. Excerpts from the updated guidelines, with the new requirements, are presented below:

FFA Guideline 18510/4 - Requirements for meat establishments approved to export to the US (Chapter 2.2 HACCP):

According to USDA requirements, the establishments are required to control zero tolerance for feces, ingesta and milk through their HACCP system in the slaughterhouse. The critical limit for feces, ingesta and milk is zero in the CCP and feces, ingesta or milk detected in the final cleaning always must lead to the cleaning of the carcass.

The establishment should choose the final cleaning, where feces, ingesta and milk can be removed, to be the CCP in slaughterhouses. Then the establishment should perform the CCP monitoring after the final cleaning and before chilling. If carcasses are cleaned at several points in the slaughterhouse, the monitoring should be done after the last final-cleaning point. If feces, ingesta or milk is observed in monitoring of the critical control point (the critical limit has been exceeded), the carcasses in question are to be cleaned before cooling. In addition to cleaning these carcasses, all carcasses that were slaughtered after the previous monitoring (last acceptable check) are to be inspected (reinspection). Records are to be kept of the monitoring and corrective actions.

FFA Guideline 18511/4 - Official control of meat establishments approved to export to the US (Chapter 1.2.4.2 Zero tolerance verification of carcasses):

According to USDA requirements, the official veterinarian must supervise the slaughtering hygiene weekly by checking the cleanliness of carcasses in the slaughterhouse after final cleaning, according to the table below. The inspection shall be carried out separately for each animal species. The entire carcass must be inspected, paying special attention to those parts of the carcasses where feces, ingesta or milk is detected most often. The lighting at the control point must be at least 540 lux (if

needed for example a flash light can be used). The OV can mark the contamination as fecal contamination only if he or she has been able to identify it as feces or ingesta based on the color or structure of the contamination and can mark contamination as milk only if he or she has been able to identify the contamination as milk based on the color and consistency. USDA has given guidance (FSIS Directive 6420.2) that milk is most commonly identified in the midline of lactating animals during or after the removal of the udder.

Both US export approved slaughterhouses have updated their own control program and working guidelines accordingly and sent them to be checked by FFA. Both establishments have now in the hazard analysis listed milk on pork carcasses to be a hazard likely to occur. It has been confirmed by FFA that the establishments also have included control for zero tolerance of milk on carcasses, in the CCP at the slaughterhouse.

Other Observations: Equipment and Utensils/Enforcement

In the establishment check lists, that are attached to the draft final audit report, it is mentioned that one of the establishments used same color and shape containers for storing edible or inedible product with no label as to which was inedible.

During the FSIS audit, the establishment stated that a container for edible products was used, as bone fragments falling from the cutting line into the container, were still at that point hygienically treated as edible products. They were not contaminated, and they were treated according to same hygienic standards as edible products, even though they were not sent to be used as food. However, the official veterinarian at the establishment immediately required the establishment to change the container to a container reserved and labeled for inedible products. The establishment was also required to without delay look through the whole cutting plant and change any possible containers reserved for edible products that were in similar use, to containers reserved and labeled only for inedible products. The official veterinarians have verified these actions during routine control activities. The establishment has also sent to the official veterinarians and FFA their updated guidance on the use and labeling of containers in the cutting plant area.

The senior officer at FFA has paid special attention to the use of containers for edible and inedible products, during regular audits to the establishment concerned, in April and June 2019. No deficiencies in the use of these containers was detected. It was confirmed that the establishment no longer used containers reserved for edible products to store inedible products in the cutting plant area.

RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Answer to FSIS Draft Final Audit Report, 2019

Microbiological Food Safety Unit
Export Section

Pvm/Datum/Date 09.07.2019

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Technical Comments Regarding the Information in the Draft Final Audit Report

The Finnish Food Act 23/2006, mentioned at page 4 includes several amendments, also after the amendment 352/2011. Unfortunately, the English translation of the Act is only available including the amendments through 352/2011, in other words until the year 2011. The latest version of the act in Finnish and Swedish can be found in the Finlex online database (https://www.finlex.fi/fi/laki/ajantasa/2006/20060023).

On page 5, it is mentioned that MFSU is responsible for the National Residue Control Program. However, nationally it is the Chemical Food Safety Unit who has this responsibility.

Statue No. 38/EEO/2006 mentioned on pages 6 and 8 in the draft final audit report has been replaced by the National Decree on Meat Inspection (590/2014).

Development of the annual residue plan as mentioned on page 13, is a collaborative effort between the Chemical Food Safety Unit, Meat Inspection Unit and Animal Health and Welfare Department of the Food Chain Division, and the Chemistry Unit, Microbiology Unit, and Risk Assessment Unit of the Laboratory and Research Division of FFA.

On page 16 it is mentioned that one of the establishments utilizes ISO 6579:2002/Amendment 1:2007, while the other establishment employs ISO 6579:2017 for analysis of salmonella samples. However, at the time of the audit both establishments already used the method ISO 6579:2017 for these analyses.

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