USDA

United States Department of Agriculture

Food Safety and
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AUG 0 2 2017

Dr. Taina Aaltonen
Ministry of Agriculture and Forestry (MMM)
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Finland

Dear Dr. Aaltonen,

The Food Safety and Inspection Service (FSIS) onsite audit conducted from January 25 through February 8, 2017, supports that Finland's inspection system continues to remain equivalent to that of the United States. 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 feel free to contact me directly.

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

# FINAL REPORT OF AN AUDIT CONDUCTED IN

# FINLAND

# JANUARY 25 TO FEBRUARY 8, 2017

# EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

# MEAT PRODUCTS

# EXPORTED TO THE UNITED STATES OF AMERICA

August 1, 2017

Food Safety and Inspection Service
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from January 25 to February 8, 2017. The purpose of the audit was to determine whether Finland's food safety system governing slaughtered and processed meat 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 the following category of product to the United States: raw, intact pork.

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 auditors identified the following systemic findings:

**Government Oversight**

- The Central Competent Authority (CCA) and/or the in-plant government officials did not provide adequate oversight. Examples include:
    - Inadequate oversight of private microbiological laboratories performing food safety testing of product eligible for export to the United States. Multiple deficiencies were identified with the laboratories' implementation of internal quality control procedures. The same finding was noted during the 2015 FSIS audit, but at a different microbiological laboratory.
    - Inadequate verification of government sanitation requirements to ensure that the establishment's corrective actions were effective to prevent the recurrence of equipment maintenance non-compliances of product contact surfaces. The same finding was noted during the 2015 FSIS audit.

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 onsite audit of Finland's food safety system from January 25 to February 8, 2017. The audit began with an entrance meeting held on January 25, 2017, in Helsinki, Finland with the participation of representatives from the Central Competent Authority (CCA) – the Finnish Food Safety Authority (Evira) and two FSIS auditors.

## 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 slaughtered and processed meat 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 raw pork product to the United States.

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) testing results, and 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 timeframe, in addition to information obtained directly from the CCA through a self-reporting process.

Representatives from the CCA and local inspection offices accompanied the FSIS auditors 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 auditors 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, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. An emphasis was placed on the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat.

Additionally, the National Reference Laboratories for chemical residue analysis and a microbiological laboratory were audited to verify their ability to provide adequate technical support to the inspection system and to assess the oversight that the CCA maintains over their functions.

| Competent Authority Visits | | # | Locations |
|---|---|---|---|
| Competent Authority | Central | 1 | • Evira / Helsinki |
| Laboratories | | 2 | • The Chemistry and Toxicology Unit – Government Residue Laboratory / Helsinki<br>• HKScan Finland Ltd. – Private Microbiological Laboratory / Vantaa |
| Pork slaughter and processing establishments | | 2 | • Est. 18 / Forssa<br>• Est. 22 / Nurmo |
| Cold storage facilities | | 1 | • Est. S061101 / Forssa |

The audit was undertaken 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 Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Finland's inspection system for slaughtered and processed meat 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 Sanitary/Phytosanitary Agreement.

Currently, Finland has equivalence determinations from FSIS for the following:

- Regulation European Commission (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 2073/2005;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC;
- Council Directive 96/23/EC; and
- Council Directive 97/747/EC.
- The CCA may allow fully trained establishment or government employees to take samples applicable to generic E. coli and *Salmonella* testing programs.
- Testing for *Enterobacteriaceae* and total viable count in lieu of testing for generic *E. coli* is acceptable for all European Union (EU) exporting countries.
- The use of an alternative laboratory testing method International Organization for Standardization (ISO) 6579:2002 (modified) for *Salmonella* by Finland is acceptable. In addition, FSIS has granted Finland equivalence for use of *Salmonella* methods ISO 6579:1993 and Nordic Committee on Food Analysis (NMKL) 71:1999.

- Finland's use of methods NMKL 147:1993 for generic *E. coli* and NMKL 144: 2005 for *Enterobacteriaceae* is acceptable.
- The use of private laboratories for the analysis of official samples is acceptable.

## III. BACKGROUND

Finland currently exports raw, intact pork to the United States. From October 1, 2013 to September 30, 2016, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 4,410,678 pounds of slaughtered and processed pork products exported by Finland to the United States. FSIS also performed re-inspection on 2,361,230 pounds at POE for additional types of inspection (TOI), none of which were rejected for food safety-related reasons.

The FSIS audit in 2015 identified the following findings:

- The CCA was using non-government employees (establishment employees) to conduct post-mortem inspection examinations when short-staffed.
- The CCA was not adequately assessing the effectiveness of corrective actions proposed by establishments to address sanitation deficiencies related to facility and equipment maintenance.

The FSIS final audit reports for Finland's food safety system are 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 auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in a such manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT), interviews, and observations made during the onsite audit.

The FSIS auditors verified that the inspection system is organized and administered by the national government of Finland. There have been no major changes in the CCA's organizational structure since the last FSIS audit. Finland is a member of the European Union (EU), has adopted the EU legislation pertaining to food of animal origin, and has based its authority to enforce inspection laws on *Regulation (EC) No. 178/2002*. This is reinforced by the *Finnish Food Act (23/2006)* and *Meat Inspection Act (1470/2011)* that has been replaced by the *National Decree on Meat Inspection (590/2014)*. The Ministry of Agriculture and Forestry (MAF) is responsible for the general planning and supervision of food and veterinary controls. Evira operates under the support of MAF, and is the agency that serves as the CCA to administer the Finnish meat inspection system. Evira is responsible for directing, planning, steering, and

carrying out food safety and animal health and welfare controls. *Finnish Food Act (23/2006)* designates Evira as the CCA for the meat inspection system. The CCA has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries.

The CCA's authority to enforce inspection laws comes from *Regulation (EC) No. 178/2002* of the European Parliament and of the Council, dated January 28, 2002, defining the general principles and requirements of food law, establishing the European Food Safety Authority, and defining 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 their national legislation and implementing regulations.

The national legislation issued by Finland to address the implementation of the meat inspection activities includes the *Finnish Food Act (23/2006)* and the *Meat Inspection Act (1470/2011)* that has been replaced by the *National Decree on Meat Inspection (590/2014).* These laws and regulations are applicable to all certified establishments. The laws and regulations provide Evira with the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States, including suspension of operations and removing the eligibility of establishments for export to the United States.

The CCA has one central office headed by Evira's Director General. The central office is comprised of three separate departments: the Administrative Department; the Research and Laboratory Department; and the Control Department. As related to meat inspection, the Administrative Department oversees Communications, Finances, Human Resources, In-house Services, Information Technology Management, Legal Affairs, Planning, and Direction. The Research and Laboratory Department oversees Chemistry and Toxicology, Food and Feed Microbiology, Pathology, Risk Assessment, Veterinary Bacteriology, and Veterinary Virology. The Control Department oversees Animal Health and Welfare, Food Hygiene, Import, Export and Organic Control (IEOCU), Meat Inspection, and Product Safety.

The IEOCU, located in Helsinki, represents the first level of the inspection system, and has direct authority over the establishments that are certified for export to the United States. There are no regional offices. The IEOCU issues guidelines and instructions that deal with the frequency of supervisory reviews; the procedures for registration, approval, conditional approval or suspension, and withdrawal of approval of regulated establishments; the verification of the microbiological sampling; the performance of official inspection tasks; and the scope and method of carrying out the National Residue Control Plan in accordance with *EC Directives 96/22* and *96/23*.

The Senior Officers (SOs) of the IEOCU are responsible for oversight of the official activities of inspection personnel and for conducting supervisory visits at establishments certified eligible for export to the United States. The CCA disseminates uniform instructions to the field via email, telephone, and hard copy to inspection personnel and establishments certified for export to the

United States. Updates and additional instructions to inspection personnel concerning established regulations, programs, and manuals are published and disseminated as guidelines.

At the local government (establishment) level, one Supervisory Official Veterinarian (SOV) has the responsibility to implement and enforce inspection requirements at the certified establishment. Each official establishment also includes Official Veterinarians (OVs) and Official Auxiliaries (OAs), which may include veterinarians, under the supervision of the SOV. The SOV and OVs are responsible for carrying out all daily inspection activities, with the OAs conducting post-mortem inspection activities.

The audit of the CCA headquarters (HQ) involved an examination of the periodic supervisory reviews at certified establishments. The IEOCU is responsible for conducting audits to determine initial and annual approval of official establishments and those eligible for export to the United States. *Finnish Food Act (23/2006), Section 13-15*, provides the procedures that establishment operators are required to follow to obtain approval from Evira to become certified for export and the actions taken by government officials at each step of the approval process. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing United States-certified establishment to maintain its eligibility to export to the United States.

*Finnish Food Act (23/2006), Section 61*, outlines the procedures for "*Cancelling the Approval of Food Premises*" by the CCA. Evira may issue a warning letter, a Notice of Intent to Delist (NOID), or cancellation based on observations made by inspection personnel for HACCP, Sanitation Standard Operating Procedures (SSOPs), or other non-compliances. If an establishment is given more than three warning letters during a period of two years, then the establishment's export approval will be removed. In addition, *Evira Manual 18511/1 - Monitoring by Officials of Meat Sector Production Plants Approved for Exporting to the USA* that has been replaced by *18511/2* describes the official veterinarians' responsibilities regarding the official process for suspension, delistment, and relisting of certified establishments.

The FSIS auditors verified elements of the certification review process for sanitation requirements, facility maintenance, SSOPs, HACCP programs, and microbial testing. The FSIS auditors observed that the CCA evaluated the written food safety programs, audited the facilities, and evaluated their compliance with FSIS requirements before granting certification of eligibility to export meat to the United States.

Finland ensures that source meat products used in processing operations originate only from certified establishments in accordance with *Regulation (EC) No. 178/200.* The CCA issued *Evira Guideline 18510/1 - Requirements for All Meat Sector Producers Approved for Exporting to the USA* that has been replaced by *18510/2. Evira Guideline 18510/2* contains the export requirements for all establishments certified as eligible for export to the United States, including control procedures to ensure that the source meat products used in processing operations originates only from certified establishments in eligible countries. The FSIS auditors verified that only pork product that originated from animals slaughtered at their own establishments was processed at the same establishment and exported to the United States.

The Finnish enforcement strategies in place are based on *Regulation (EC) No. 882/2004, which is implemented through Finnish Food Act (23/2006)* and *Evira Guideline 18511/2*. The *Finnish Food Act (23/2006), Chapter 10,* explains the penalties for health offenses that violate the provisions of the act. FSIS verified that the CCA prevents fraud or misuse of export health certificates by issuing export health certificates on secure watermarked paper. A tracking system is in place at the CCA headquarters and at the establishment level by the OVs who maintain all export health certificates, government seals, and security accountability logs in a secured, locked environment.

Evira is an agency funded by the national government whose revenue includes fees assessed to meat establishments as provided under the authority of *Finnish Food Act 23/2006, Chapter 8*, which outlines the criteria for charges for services carried out by government authorities. All Evira personnel are employees of the government of Finland and subject to administrative policies that apply to all government officials.

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. Inspection personnel at establishments certified to export meat to the United States are required to be employees of the national government. Evira assigns inspection personnel via certificates of appointment to establishments eligible to export products to the United States.

During the 2015 FSIS audit, the FSIS auditor identified that Evira allowed the SOVs at establishments to request the temporary employment of establishment employees to conduct post-mortem inspection of the heads and viscera for Evira when there is a short-term shortage of Evira OAs for post-mortem inspection, and there is no available alternative to staff the slaughter inspection line. The CCA took immediate action to officially stop the practice when it was initially identified by FSIS during the audit of the first establishment. The CCA then issued a letter on March 16, 2015, to the certified establishments that officially stopped the practice of using establishment employees to conduct post-mortem inspection duties. The CCA instructed the SOVs that they would only use official inspection personnel to conduct all related inspection duties. Additionally, Evira proposed to hire additional government employed OAs to conduct inspection activities when there was a shortage of staff at establishments that were certified for export to the United States.

During the 2017 FSIS audit, the FSIS auditors reviewed Evira's "certificate of appointment" document of the inspection personnel for new "relief" OAs. The FSIS auditors cross-referenced the inspection personnel hired with a document review of Evira employee inspection rosters, recorded accountable time worked by inspection personnel at the establishments and interviewed Evira in-plant inspection SOVs to verify that Evira employs all inspection employees. The FSIS auditors verified that all inspection personnel conducting government verification activity, including ante- and post-mortem inspection are government-paid employees, as defined in *Statute No. 38/EE/2006* that has been replaced by the *National Decree on Meat Inspection (590/2014)* and *Finnish Food Act 23/2006, Chapter 6*, and received pay stubs to verify that the CCA operations are funded by the government budget, in accordance with the act.

The FSIS auditors evaluated actions implemented by the CCA in response to the 2015 FSIS audit finding and identified that in the event of staffing shortages, the SOV or OV contacts an OA from an official list of approved "relief" OAs to conduct post-mortem inspection duties at the establishment. The FSIS auditors verified that all local establishment inspection employees including available "relief" OAs are direct employees of the government and receive the same training as permanent inspection personnel at certified establishments, thus ensuring that the 2015 FSIS audit deficiency was addressed and meets FSIS requirements.

At establishments that are certified for export to the United States, each SOV and/or OV conducts, and observes daily inspection activity, and reviews daily records that document the activities. The FSIS auditors' review of these records confirms that an SOV or OV was at each audited establishment each day of the week that inspection was required and that government inspectors were on the post-mortem slaughter line during all slaughter operations.

In accordance with *Regulation (EC) No. 854/2004*, Finland ensures that inspection personnel have appropriate education credentials, and necessary training and experience to carry out inspection tasks. The CCA 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. OAs, in accordance with *Regulation (EC) No. 854/2004*, have inspection courses involving practical training on the slaughter line and theoretical class work, after which they must pass specific examinations before being qualified to work in export meat establishments. The CCA, in cooperation with the University of Helsinki, provides these training courses for OVs.

The FSIS auditors 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 CCA conducted training sessions routinely since the last FSIS audit in 2015 associated with exports, including granting export health certificates, controls, and traceability. In addition, Evira annually organizes and presents a one-day training course to inspection personnel on United States export issues, including HACCP, SSOPs, and sanitation requirements. The FSIS auditors verified the training records of OVs and OAs in addition to observing in-plant inspection personnel while they were conducting their inspection activities and concluded that that they have sufficient training to perform their duties.

The CCA maintains administrative and technical support to operate its laboratory system. The laboratories are under the immediate authority of Evira. Coordination and communication occur between the Food Safety Steering Group and Evira to develop the National Residue Control Program Plan according to *Council Directive 96/23/EU* and microbial sampling plans to ensure that Evira meets United States requirements. The CCA includes two government laboratories. The Chemistry and Toxicology Research Unit performs official chemical residue analyses and has been identified as the National Reference Laboratory for all commodities and all substance groups listed in *Annex 1 of Council Directive 96/23/EU*. The Kuopio Research Unit is responsible for confirming and serotyping the positive *Salmonella* results. In addition, two private laboratories perform microbiologic analyses for *Salmonella* and generic *E. coli* analytical testing.

The CCA approves the eligibility of private laboratories for conducting microbiological testing in accordance with *Finnish Food Act (23/2006)* requirements. All laboratories operate in accordance with criteria aligned with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standard. Government and private laboratories are accredited by the Finnish Accreditation Service (FINAS) every four years with periodic surveillance audits carried out once a year for ISO/IEC 17025 accreditation. *Finnish Law 921/200*5 establishes FINAS as the national accreditation body responsible for organizing the accreditation activities according to the international criteria.

The FSIS audit included onsite visits to one government residue and one private microbiological laboratory to verify the functions and oversight provided by the CCA. The FSIS auditors reviewed the two most recent FINAS audits and internal laboratory audit reports generated for the previous year at CCA HQ and at the audited laboratories. No concerns arose as the result of these reviews. FSIS' onsite audit did not identify any issues with the government chemical laboratory. However, the FSIS auditors identified the following:

- The private microbiological laboratory did not monitor the temperatures of 1 of 3 incubators, specifically the incubator used for storing the *Salmonella* confirmation tests on XLD and Rambach plates on the weekend and off days. The laboratory monitors the temperature of the incubator once daily (manually) during the workweek (Monday-Friday) only when employees are working.
- The private microbiological laboratory did not follow procedures for monitoring ingredients, nor did they follow the testing methods as written in the laboratory's quality assurance manual. Examples include:
  - Rambach prepared plates were stored in a refrigerator that was maintained at 4° Celsius +/- 1° Celsius. The instructions in the Rambach box stated the prepared medium should not be stored below 6° Celsius.
  - A bottle of plate count agar was in use but the date of opening had not been recorded on the outside of the bottle.
  - A bottle of Brain Heart Infusion Broth that expired in December 2016 had not been discarded at the time of the audit.

The FSIS auditors' review of the 2015 FINAS annual audit reports of the microbiological laboratory did not identify any of the above findings. Although the above listed finding did not have a direct impact on food safety, the same findings from the previous FSIS audit indicates an insufficient CCA oversight of the private laboratory quality control, which could affect test results.

FSIS 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.

## 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 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 carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations during the onsite audit. Since the last audit, there have been no regulatory changes associated with the export of meat products to the United States that would have required changes by the CCA.

The FSIS auditors verified that the CCA maintains regulatory authority as outlined in official legislation, regulations, decrees, policies, and guidelines. The CCA's authority is in accordance with the following:

- *Regulation (EC) Nos. 178/2002* and *852/2004* on the hygiene of foodstuffs;
- *Regulation (EC) No. 853/2004* describing specific hygiene rules for the food of animal origin;
- *Regulation (EC) No. 854/2004* describing specific rules for the organization of official controls on products of animal origin intended for human consumption;
- *Regulation (EC)* No. *882/2004* on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- *Decision 98/258/EC* on the conclusion of the agreement between the EC and the United States on sanitary measures to protect public and animal health in trade in live animals and animal products;
- *Finnish Food Act (23/2006)* aims to ensure the safety and quality of foodstuffs and protects consumers against health hazards. It also ensures correct and sufficient information on foods, traceability and control.
- *Evira Guideline 18510/2* details requirements for meat inspection systems in all official establishments eligible for export to the United States; and
- *Evira Manual 18511/2* provides instructions to Evira in-plant personnel.

The FSIS auditors reviewed records maintained at CCA HQ and local inspection offices in each audited establishment. The FSIS auditors verified whether the CCA provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for Finland's meat food safety system. The FSIS auditors, accompanied by the CCA representatives, observed the performance of verification activities by the in-plant inspection personnel.

The verification activities observed included ante-mortem inspection; humane handling and slaughter verification; post-mortem inspection; zero-tolerance verification of establishment's procedures for controlling of feces, ingesta, and milk contamination; *Salmonella* Performance Standard sample collection; analysis of establishment generic *E. coli* sample results; verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities. Additionally, the FSIS auditors assessed the performance evaluation of in-plant inspection personnel and the completion of supervisory reviews of establishments certified eligible for export to the United States.

The FSIS auditors verified that in-plant inspection personnel's ante-mortem inspection activities complied with EU regulations and *Evira Manual 18511/2*. 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 the USDA's Animal and Plant Health Inspection Service are designated for export to the United States. The inspection personnel reviewed the incoming registration and identification documents with each load/truck and observed all animals from both sides while at rest and in motion in unloading and ante-mortem inspection pens before slaughter in order to determine whether the animals are fit for slaughter. The FSIS auditors observed and verified that all animals had access to water at all times in holding pens, including the suspect pen and that if an animal were to be held overnight feed would be provided. For each inspected lot, the Evira personnel document the results of ante-mortem inspection and numbers of livestock on pen cards accompanying each lot to slaughter.

Each audited establishment maintained a designated holding pen for further examination of sick or suspect animals. The OV examines any suspect livestock, identified with conditions that may preclude slaughter, and documents results on a form, designated for ante-mortem inspection. Additionally, the OV documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form and all products are rendered unsuitable for human food with denaturant prior being rendered as required by *Statute No. 38/EEO/2006* has been replaced by the *By-Products Regulation ((EC) No 1069/2009)* and the *National By- Product Act (517/2015)*. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock.

The FSIS auditors verified whether the inspection system ensures United States requirements are met for livestock facilities and humane handling and slaughter. In-plant inspection personnel verify that operators comply with humane handling and slaughter requirements. The FSIS auditors observed the stunning process at audited establishments and verified that each establishment utilized a carbon dioxide gas chamber and verified adequate stunning prior to shackling and hoisting. The Evira personnel also verify gas concentration and its exposure time to render swine insensitive to pain. The Evira personnel also observe the loss of consciousness and accompanying indicative signs of adequate stunning before swine are shackled and bled.

The Evira personnel document results of humane handling and slaughter verification on the designated verification form, and Monitoring Plan Verification form. EU regulations and the *Animal Welfare Act 247/1996* (amendments up to 1430/2006), specify the requirements of

humane handling and slaughter of livestock in the slaughter establishments, including that animals will have access to water in all the pens.

The CCA has defined the number of Evira personnel required for each establishment. The presence of an OV during post-mortem examination is mandated in *Chapter II of Section III of Annex I of Regulation (EC) 854/2004*. The SOV is responsible for supervising on-line OAs and post-mortem inspection activities, including disposition of suspect carcasses and parts by OVs. *Regulation (EC) No. 854/2004, Annex I,* provides that line speeds and the number of inspection personnel assigned allow for proper inspection. The FSIS auditors verified that the Evira SOVs at each establishment were aware of the required staffing and that the number of OAs conducting post-mortem inspection activities is sufficient for the existing production volume and line speed in all audited establishments. Personnel were also assigned to perform off-line verification activities such as ante-mortem inspection of animals in motion and at rest, collection of samples for laboratory analyses, and verification procedures in the deboning rooms.

The FSIS auditors verified that written procedures are in place instructing inspection personnel how post-mortem inspection is to be performed, including visual inspection, palpation, and incision of relevant portions of the animal described in *Regulation (EC) No. 854/2004*. The FSIS auditors verified through direct observation the post-mortem inspection by Evira personnel to verify implementation of proper presentation, identification, examination, and disposition of carcasses and parts. The FSIS auditors observed OAs performing examination of swine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes. Evira post-mortem examinations are in accordance with EU regulations, which have been recognized as equivalent to FSIS requirements.

The FSIS auditors observed the off-line OVs conducting daily inspection and verification activities in all three audited establishments and verifying that government inspection occurs at least once per shift during the processing of meat products. Disposition of suspect animals during ante-mortem and post-mortem inspection, and verification of acceptability of the final product, are the responsibility of the OV, who prepares daily post-mortem disposition reports to document his/her official control actions. The Evira verification procedures and instructions are documented in *Evira Manual 18511/2*. This document also details specific instructions for verification of United States requirements.

The OV verification activities include direct observation and record review procedures related to SSOPs, sanitation, HACCP, residue sampling, and *Salmonella* spp. and generic *E. coli* sampling techniques and records in accordance with the Supervisory Monitoring Plan. The CCA has developed specific risk-based verification frequencies and each establishment SOV is responsible for drafting monitoring plans based on those frequencies, which include yearly and weekly schedules. The SOV then ensures that inspection personnel perform verification procedures at the frequency identified in the monitoring plan with results documented electronically.

At each audited establishment, the FSIS auditors observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during dressing procedures and viscera removal. The FSIS auditors also observed in-plant inspection

personnel conducting verification of monitoring of the critical control point (CCP) for zero-tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors did not observe any systemic sanitary dressing concerns or zero tolerance deviations during the audit.

The FSIS auditors reviewed and verified the documentation of conducted CCA supervisory reviews of certified establishments at CCA HQ and audited establishments. The reviews consist of the evaluation of the adequacy of establishments' food safety systems and delivery of official inspection and verification services. The SO of the IEOCU in accordance with *Evira Manual 18511/2 and Evira Guideline 18510/2* conducts these reviews. These documents contain instructions to inspection personnel, including procedures regarding implementation comprising frequency of verification; documentation; and corrective actions for Sanitation, HACCP, *Salmonella* sampling, and *E. coli* sampling.

The SO performs supervisory visits to meet 9 CFR Part 327.2 requirements and the Evira requirements that the audits are conducted six times for slaughter and processing establishments and two times for cold storage facilities per year at every certified establishment. The FSIS auditors reviewed multiple supervisory visit reports conducted over the prior 12 months that confirmed the frequency of supervisory visits at each certified establishment. The supervisory reviews were conducted using a uniform detailed form. The supervisory reviews evaluate the adequacy of the establishments' food safety systems and the capability of inspection personnel to conduct inspection activities at certified establishments.

FSIS' assessment of documentation associated with supervisory reviews at establishments indicated that these reports were well documented, identifying both positive and negative results with the latter having documented actions resolved expediently and verification of those actions by the OV. The SO on the next audit verified that the corrective actions for all identified deficiencies had been implemented and verified by the inspection personnel. The FSIS auditors did not identify any negative trends based on the supervisory review records and inspection-related verification activity records reviewed.

The FSIS auditors 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. The EU regulations and *Evira Guideline 18510/2* contain requirements that establishments approved for export to the United States ensure complete separation of product eligible for export to the United States. In-plant personnel verify requirements for separation of products and document results on the Supervisory Monitoring Plan record. The FSIS auditors verified use of product codes with designated codes for export to the United States and segregation of final boxed product. The FSIS auditors verified that establishments had written programs to define separation of products destined for export to the United States.

The FSIS auditors verified that the CCA has adequate verification procedures to ensure United States requirements are met. In addition, the CCA has consistently ensured the implementation of sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present.

## VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations during the onsite audit.

The FSIS auditors reviewed the legislation, regulations, official instructions, decrees, and guidelines of the CCA and verified that Evira uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditors' verification activity identified in this component demonstrated that the CCA enforces overarching EU sanitary regulations, including *Regulation (EC) No. 852/2004 Article 4 No. 2 cf.; 4 No. 3* and *Annex II; 853/ 2004 Article 3 cf. Annex II Chapter I-VII*, and *Annex III; 854/2004 Article 4(2)*, which have been determined to be equivalent to FSIS requirements. In addition, Finland incorporated FSIS regulations in 9 CFR Part 416 into its export requirements for the United States.

The *Finnish Sanitation Guideline No. 662/32/03* that has been replaced by *Evira Guideline on Risk Based Control of Food Establishments 16044/1* and *Evira Guideline 18510/2* provide instructions for establishments eligible to export to the United States in accordance with FSIS 9 CFR Part 416 sanitation requirements. *Evira Manual 18511/2* provides instructions to in-plant inspection personnel at certified establishments for the verification of FSIS 9 CFR Part 416 sanitation requirements. These documents include the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational sanitation procedures. The frequency of sanitation inspection verification tasks is risk-based and Sanitation SOP verification is set as daily for inspection personnel.

The CCA demonstrated that it enforces these requirements at certified establishments. The CCA conducts verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures, including hands-on verification inspection, and records review. The FSIS auditors verified the verification frequency of sanitation requirements as they vary as yearly, monthly, weekly, and daily and are scheduled in the Supervisory Monitoring Plan. The Evira personnel conduct verification of sanitation SOP requirements daily.

The FSIS auditors assessed the adequacy of pre-operational sanitation by observing Evira personnel conducting pre-operational verification of the establishment's sanitation program at one of the audited establishments. The in-plant inspection personnel conducted this activity in accordance with the established procedures including a pre-operational record review of the establishment monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils; as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity).

The FSIS auditors observed Evira in-plant inspection personnel's verification of operational sanitation procedures in all three audited establishments, comparing the overall sanitary conditions of all audited establishments to the Evira inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records over a 3-month period at all establishments. The FSIS auditors also examined the Evira documentation of inspection verification results documented in the Supervisory Monitoring Plan, and non-conformance/non-compliance reports and supervisory reviews of establishments. The FSIS auditors noted for the most part that the inspection and establishment records were reflective of the actual sanitary conditions of the establishment.

The FSIS auditors identified sanitation findings at two audited establishments reflective of the CCA's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations. The FSIS auditors reviewed the Evira and establishment records and identified instances of non-compliance as described in the following:

- The FSIS auditors observed the in-plant inspection personnel conducting pre-operational verification of the establishment's sanitation program. Several deficiencies were noted on various types of conveyor belts that come into contact with exposed product.

The in-plant inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination. The CCA further provided the FSIS auditors with evidence that the equipment non-compliances had been corrected and verified to ensure compliance with United States requirements.

The 2017 FSIS audit identified the same finding, observed during the 2015 FSIS audit, which identified deteriorated conveyor belts at both slaughter and processing establishments. In response to the 2015 audit findings, the in-plant inspection personnel began inspecting conveyor belts once per week as part of their verification of operational sanitation. The establishment implemented a conveyor belt inspection program that included monthly inspection by the maintenance department and daily inspection by the sanitation department. The FSIS auditors reviewed the CCA's most recent supervisory review. It did not identify any deficiencies in the maintenance of conveyor belts; however, review of recent non-compliance reports indicated that in-plant inspection personnel had observed and documented inadequate maintenance of conveyor belts on November 3, 2016.

The continued observance of deficiencies relating to conveyor belt maintenance indicates the 2015 corrective actions and measures to prevent the recurrence taken by the establishment were ineffective. The CCA's monitoring of the 2015 FSIS audit corrective actions was ineffective.

The FSIS auditors' analysis and onsite verification activities indicate that the meat inspection system of Finland requires that all certified establishments develop, implement, and maintain sanitation programs, including SSOPs, to prevent the creation of insanitary conditions and direct product contamination. Inspection personnel conducting verification on the implementation adequacy of sanitation programs assess the risks posed by conditions that could cause direct product contamination, and when a non-compliance is identified, they require the establishment to implement adequate corrective actions.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations during the onsite audit.

Finland adopted FSIS requirements cited in 9 CFR Part 417 for the implementation of HACCP. The CCA, through *Finnish Food Act (23/2006), MMM Statute 795/2014, and Evira Guideline 18510/2*, requires that establishments exporting to the United States develop, implement, and maintain HACCP programs that must be reviewed and approved by the CCA. The auditing unit of Evira conducts the HACCP program reviews and auditing activities. The design and implementation of all certified establishments' HACCP programs are reviewed yearly, prior to the granting of export certification renewal.

At the two audited slaughter and processing establishments, the FSIS auditors conducted an onsite review of the establishments' HACCP system, including hazard analyses, HACCP plans, and CCP records. The FSIS auditors observed the Evira personnel conducting HACCP hands-on verification activities at each audited establishment. In addition, the FSIS auditors reviewed the in-plant inspection HACCP verification records associated with CCPs documented on the electronic Supervisory Monitoring Plan record. The review of the establishments' corrective actions in response to a few deviations from critical limits indicated that the establishments' corrective actions were adequately documented and verified by Evira personnel as meeting all HACCP corrective action requirements in 9 CFR 417.3(a). For each corrective action, Evira personnel also documented the elements of the corrective action and Evira verification results on the electronic Supervisory Monitoring Plan record.

The FSIS auditors' review of documents pertaining to the hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments as well as onsite observation of the inspection personnel conducting inspection tasks and associated inspection verification records, revealed an adequate HACCP food safety system in the audited establishments. The establishments complied with Evira's *HACCP Guideline No. 10002/2* and adopted FSIS requirements in 9 CFR Part 417.

The FSIS auditors' analysis and onsite verification activities indicate that the CCA requires operators of establishments certified for export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

## VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The 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 and poultry inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed the Finland National Residue Control Program for 2016, 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.

FSIS based its verification of Finland's chemical residue testing program on information contained in Finland's Annual Residue Control Plan for 2016, which included 2015 testing results. Finland's national residue control program is based on EU legislation (*Council Directive 96/23/EC of 29 April 1996* and *Council Directive 96/22/EC of 29 April 1996*), the *Finnish Food Act 23/2006*, and it is implemented in accordance with the *Decree of Ministry of Agriculture and Forestry on Residues in Foodstuffs of Animal Origin (1/EEO/2007*), which provides the legal basis for the annual residue plan. These documents prescribe conditions of chemicals used in the production of meat, including animal feed; provide authority to prohibit the use of compounds that may present public health risks; and provide the ability to control and monitor industrial and environmental chemicals. These documents also indicate that Evira maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

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 Evira. 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, 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 FSIS auditors verified that the CCA oversees the implementation of its national residue control program. The CCA maintains this through an annual audit of the residue laboratory conducted by FINAS. The FSIS auditors reviewed the most recent audit report for the Chemistry and Toxicology Research Unit conducted on October 25-27, 2016 and found no issues. The scope of the audits conducted by FINAS included administrative and technical controls of the laboratory that analyzes samples from certified establishments.

The FSIS auditors verified implementation of the national residue monitoring plan (NRMP) at the audited establishments. The Food Hygiene Unit of Evira provides instructions to Evira personnel collecting samples for residue analyses, including a scheduled sampling plan. The plan lists the residue group, the number of samples for the group, and the matrix for each month. The individual OVs randomly select the carcass to sample. The OVs complete the laboratory submission form, and a copy is packaged in the sample shipment cooler, which Evira secures with a numbered seal to maintain integrity. The CCA's prescribed sampling protocol mandates

test and hold practices to ensure that Evira verifies acceptable residue results prior to issuing certification for export to the United States. In the event any sampled lot has violative levels of a chemical compound, the OV also issues a non-conformance/non-compliance report to the establishment. FSIS' review of documentation at the two audited local inspection offices indicated that in-plant government inspection personnel were collecting samples of the required matrices for detection of specific analytes and adhering to the prescribed sample collection schedule. FSIS' review of the monitoring results for 2015 indicates that no violative samples were detected.

In addition, the FSIS auditors performed an onsite audit of the Evira Chemistry and Toxicology Research Unit, which serves as the official laboratory conducting analyses of government samples for the presence of chemical residues in meat products, and is the National Reference Laboratory for all commodities and all substance groups listed in *Annex 1 of Council Directive 96/23/EC*. The Chemistry and Toxicology Research Unit conducts the majority of all NRMP analyses. The FSIS auditors verified the FINAS scope of accreditation, equivalent to EN ISO/IEC 17025:2005. The most recent accrediting body audit by FINAS included an action plan for identified findings that the laboratory submitted to FINAS. The FSIS auditors verified corrective actions for each FINAS audit finding including verification signatures and dates from the laboratory personnel responsible for implementation. The laboratory performs internal audits and implements an action plan to address each internal audit finding. The Chemistry and Toxicology Research Unit records and past internal laboratory audit reports demonstrate that laboratory managers readily respond to and correct non-conformities identified during internal and external audits.

The FSIS auditors verified receipt of samples in the Chemistry and Toxicology Research Unit. At sample receipt, the laboratory verifies the seal is intact and matches the number on the laboratory submission form. The laboratory verifies and documents the temperature of the sample and, once verification confirms sample integrity, the laboratory assigns a unique laboratory sample number. The Chemistry and Toxicology Research Unit rejects the sample if requirements are not met or sample integrity is not maintained. The laboratory sample number alone accompanies the sample through the analytical process to eliminate any potential bias.

The Chemistry and Toxicology Research Unit reports results to the CCA on an official form. The CCA official control measures and enforcement actions are in accordance with *Council Directive 96/23/EC of 29 April 1996* and defined in *Chapter IV,* and in the event a sample exceeds tolerances, the Chemistry and Toxicology Research Unit notifies the CCA and OV via electronic mail. The following procedures are followed by the CCA when a sample exceeds tolerances: they are to identify the animal and farm of origin; investigate the cause of the violation at the farm; safeguard the public health by product disposition; intensify the checks on the animals and products from the farm; and impose criminal or administrative penalties against any person who is responsible. Finland, as a member of the EU, has residue plans that are acceptable by EU standards and therefore recognized as equivalent to FSIS' criteria.

The FSIS auditors verified that Evira has implemented the NRMP in accordance with *Council Directive 96/23/EC of 29 April 1996*. The CCA has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet FSIS criteria. The program

contains provisions that ensure any product with residues exceeding established tolerances is condemned and ineligible for use as human food. In addition, to prevent the violations from recurring, the CCA investigates the cause of the residue violation and initiates intensified sampling from the same supplier.

## IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, as well as interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the 2015 FSIS audit.

The evaluation of this component included a review and analysis of *Regulation (EC) No. 2073/2005 of November 15, 2005, on Microbiological Criteria for Foodstuffs*, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. Specific rules for testing and minimum sampling are provided in *Regulation (EC) No. 2073/2005*. Finland has equivalence determinations in place that allows either trained establishment or government employees to take samples applicable to generic *E. coli* and *Salmonella* testing programs.

Finland requires all slaughter establishments to implement an establishment conducted microbiological testing program for *Enterobacteriaceae* to verify process control. The inspection system provides for a sampling and testing program for generic *E. coli* or *Enterobacteriaceae* in raw meat product. *Enterobacteriaceae* testing has been accepted as equivalent to generic *E. coli* by FSIS; however, establishments that are certified eligible for export to the United States have the option of conducting generic *E. coli* testing instead. The FSIS audit included direct observation, record review, and interviews of Evira and private microbiological laboratory personnel to verify microbial process control. Finland has adopted "same as" United States requirements found in 9 CFR 310.25(a) for generic *E. coli*, with the exception of the following equivalent measures: Finnish establishments use a gauze swab sampling tool and accredited private microbiology laboratories use an Association of Analytical Communities (AOAC) approved NMKL method or AOAC Petrifilm method to analyze samples for generic *E. coli*. *E. coli* sampling is in accordance with adopted 9 CFR 310.25 for generic *E. coli* and *Regulation (EC) No. 2073/2005* for *Enterobacteriaceae*.

The CCA conducts verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. The Evira in-plant personnel verify establishment sampling collection methodology in 10 percent of samples through direct observation and its secure submission of each sample to the private microbiological laboratory for analysis. In addition, the CCA verifies the establishment

sampling collection methodology once a year through Supervisory Reviews. The CCA uses the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, the in-plant inspectors verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded. The CCA requires that test results for product that is presented for export to the United States be found compliant prior to the export health certificate being approved. Additionally, the CCA mandates that all establishments have a recall program in place and a trace back system for product produced.

The FSIS auditors verified through document reviews and direct observation that the two audited slaughter and processing establishments had implemented a generic *E. coli* testing program to verify process control of livestock carcasses in accordance with 9 CFR 310.25(a). The FSIS auditors reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. The FSIS auditors' review of the establishments' generic *E. coli* testing programs and the establishments' records did not reveal any non-compliance or concerns.

The CCA has a *Salmonella* spp. sampling and testing program in raw product to meet *Salmonella* Performance Standards requirements. Finland's national *Salmonella* control program is to keep the prevalence of *Salmonella* in pork products and in living swine animals below one percent. *Salmonella* sampling requirements are based on 9 CFR 310.25(b), the *Finnish National Salmonella Regulation No. 20/EEO/2001* has been replaced by *National Decree on Salmonella control in meat establishments (134/2012),* and *Evira Guideline 18510/2*. The FSIS auditors reviewed implementation of the program within certified establishments along with results and records documenting performance standards. The frequency of *Salmonella* sampling and testing is set by the CCA. It includes both carcasses and ileocecal lymph nodes for *Salmonella* spp. and occurs in all certified establishments that slaughter livestock.

Finland has an establishment conducted microbiological testing program for *Salmonella*. The in-plant personnel observe 10 percent of samples collected and the CCA observes sample collection once per year. The establishments submit all samples to the private microbiology laboratory for analysis for presence of *Salmonella* spp. Evira verifies that all certified establishments' sample collection procedures are in accordance with the sample collection protocols described in the aforementioned regulatory requirements. The planning of the in-plant inspection verification is made in accordance with *Evira Manual 18511/2*. Evira performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/pathogen reduction studies) to determine the ongoing effectiveness of the inspection system for *Salmonella* Performance Standards.

The FSIS auditors reviewed records, including *Salmonella* spp. results, for the last year at the two audited slaughter and processing establishments. Results showed no *Salmonella* set failures during the period reviewed. In addition, the FSIS auditors accompanied and observed the in-plant inspection verification activities to verify aseptic technique, and procedures for sample collection from porcine carcasses for *Salmonella* testing in one of the audited establishments. The demonstrated methodology is consistent with FSIS' method. No concerns arose because of these observations and reviews.

The CCA accredited establishment private laboratories are required to use methodology approved by the CCA. ISO 6579-2002 is the testing method used for the detection of *Salmonella*. The CCA approves and FINAS performs annual audits of establishment laboratories. The establishment is responsible for reporting results to the CCA.

The FSIS auditors performed an onsite audit of the HKScan Finland Ltd. Microbiological Laboratory in Vantaa, the private laboratory. The laboratory performs inspection system analyses for generic *E. coli*, *Salmonella* spp., and *Salmonella* serotype. The FSIS auditors verified that FINAS has accredited the laboratory as equivalent to the ISO/IEC 17025:2005. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support Evira's inspection program for certified establishments eligible for export to the United States.

FINAS audits the private microbiological laboratories annually. Each FINAS audit is partial so that it takes 4 years to complete an audit of the entire laboratory system. The FSIS auditors reviewed the most recent audit report, performed by the accrediting authority. The laboratory also performs internal audits according to their Quality Assurance Manual. The laboratory has procedures for proficiency testing. The CCA verifies that United States equivalent methods are used for samples from certified establishments. During the CCA HQ audit, the FSIS auditors reviewed the two most recent FINAS annual audit reports of the laboratory. There were no findings from the document review; however, the FSIS auditors identified issues relating to the private microbiological laboratory's quality management system, which were addressed in the Government Oversight component.

The FSIS auditors observed and verified sample receipt and handling. The FSIS auditors verified that the private laboratories perform a timely analysis of samples, and that they report the amount of analyzed samples and the results every month to Evira in a timely manner, apply approved analytical methodologies, and have quality assurance programs. No concerns arose because of these observations and reviews. The FSIS auditors verified that FINAS conducts the prescribed annual audit of the laboratory quality system to ensure United States requirements are met.

The FSIS auditors' document analysis and on-site verification activities demonstrate that Finland's meat inspection system includes requirements for a microbiological sampling and testing program. It is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The microbiological testing program as described is consistent with the criteria established for this component.

## X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on February 8, 2017, in Helsinki, Finland with Evira. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

The current audit did not identify any concerns that represented an immediate threat to public health. During the audit exit meeting, the CCA committed to begin to address the preliminary

systemic findings as presented and provided additional evidence that many of isolated findings related to sanitation and HACCP described on the individual establishment checklists (Appendix A) had been addressed.

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

**Government Oversight**

- The CCA and/or the in-plant government officials did not provide adequate oversight. Examples include:
    - Inadequate oversight of private microbiological laboratories performing food safety testing of product eligible for export to the United States. Multiple deficiencies were identified with the laboratories' implementation of internal quality control procedures. The same finding was noted during the 2015 FSIS audit, but at a different microbiological laboratory.
    - Inadequate verification of government sanitation requirements to ensure that the establishments' corrective actions were effective to prevent the recurrence of equipment maintenance non-compliances of product contact surfaces. The same finding was noted during the 2015 FSIS audit.

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 base 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.<br>Teollisuuskatu 17<br>Forssa | 01/27/2017 | 18 | 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 | Part D - Continued Economic Sampling | Audit Results |
|---|---|---|---|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| **Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements** | | **Part E - Other Requirements** | |
| 10. Implementation of SSOP's, including monitoring of implementation. | | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| **Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements** | | 40. Light | |
| 14. Developed and implemented a written HACCP plan . | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| **Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements** | | 45. Equipment and Utensils | X |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | X |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | **Part F - Inspection Requirements** | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| **Part C - Economic / Wholesomeness** | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| **Part D - Sampling Generic *E. coli* Testing** | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | **Part G - Other Regulatory Oversight Requirements** | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | X |
| 29. Records | | 57. Monthly Review | |
| **Salmonella Performance Standards - Basic Requirements** | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Pre-Operational Observations:

45/51 Equipment Maintenance:
56

During the FSIS auditors' observation of pre-operational sanitation verification by Evira multiple deficiencies in the maintenance of conveyor belts that come into contact with exposed product were identified by the Supervisory Official Veterinarian in the Fabrication Department. Deficiencies identified included plastic conveyor belts which were made up of hinged, interlocking plastic segments included multiple broken hinged plastic segments and that vinyl conveyor belts had frayed edges and were in a deteriorated condition.

Immediate corrective actions were taken by the establishment and verified by Evira with additional measure to prevent the reoccurrence be provide to inspection personnel.

During the 2015 FSIS audit, similar deficiencies were identified relating to conveyor belt maintenance. The establishment's previous corrective actions included development of a conveyor belt inspection program that includes once monthly inspection by the maintenance department and daily inspection by the sanitation department. Additionally, Evira increased inspection verification task that verifies conveyor belts once a week as part of their operational sanitation verification task. These preventative measures do not appear to be effective at preventing reoccurrence.

FSIS auditors did identify that the establishment and Evira have identified deficiencies with maintenance of equipment. Evira's verification of actions taken by the establishment to prevent the reoccurrence of these types of deficiencies does not appear to be effective or have not been properly implemented by Evira.

46/51 Sanitary Operations - Sanitary Dressing Procedures
56

During the auditors walkthrough of the establishment pork fabrication department and carcass holding coolers the FSIS auditors observed a deficiency in that multiple carcasses and carcass parts that are further processed were identified with clusters of long hair (2 inches in length) and larger areas of shorter hair (1 inch in length) that was not removed from the swine carcass during the slaughter dressing process.

It should be noted that the carcass parts that were staged for further processing were layered on stainless steel tree hooks where the hair can come in contact with the exposed meat surface when layered on the hook. This creates a potential cross contamination condition in the processing of the carcasses and parts. These observations indicate ineffective sanitary dressing and process control procedures which are crucial to an establishment's ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

Evira will provide FSIS measures taken to address the identified sanitary dressing deficiencies.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|---|---|
| OIEA International Audit Staff (IAS) | 01/27/2017 |

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.<br>Lapuantie 594<br>NURMO | 01/31/2017 | 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. | |
| 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 | |
| 52. Humane Handling | |
| 53. Animal Identification | |
| 54. Ante Mortem Inspection | |
| 55. Post Mortem Inspection | |
| **Part G - Other Regulatory Oversight Requirements** | |
| 56. European Community Directives | X |
| 57. Monthly Review | |
| 58. CCA Zero-Tolerance Verification | X |
| 59. | |

60. Observation of the Establishment

58/56 CCA Zero-Tolerance Verification

During the auditors walkthrough of the establishment pork slaughter department FSIS auditors were presented with a demonstration of the Evira off line inspection personnel conducting the inspection verification of zero-tolerance at the stand located after post mortem inspection and prior to entering the cooler. Though no zero-tolerance issues were identified during the audit, it was observed that the off line veterinarian did not adequately examine the outer surfaces of the entire carcass while conduct zero-tolerance verification of the carcass to evaluate sanitary dressing procedures.

Additionally, a review of 90 days of establishment and inspection verification documents provided no evidence of zero-tolerance failures or issues with sanitary dressing procedures.

Evira will provide FSIS measures taken to address the FSIS's identified concern with inspection verification task procedure.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|---|---|
| OIEA International Audit Staff (IAS) | 01/31/2017 |

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<br>Teollisuuskato 17<br>Forssa<br>Etelä-Suomen lääni (fi) | 01/26/2017 | 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 | 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. Enforcement | |
| 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 | O |
| **Part D - Sampling Generic *E. coli* Testing** | | 55. Post Mortem Inspection | O |
| 27. Written Procedures | O | **Part G - Other Regulatory Oversight Requirements** | |
| 28. Sample Collection/Analysis | O | 56. European Community Directives | |
| 29. Records | O | 57. Monthly Review | |
| **Salmonella Performance Standards - Basic Requirements** | | 58. | |
| 30. Corrective Actions | O | 59. | |
| 31. Reassessment | O | | |
| 32. Written Assurance | O | | |

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
| --- | --- |
| OIEA International Audit Staff (IAS) | 01/26/2017 |

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

Evira

ANSWER TO FSIS
DRAFT FINAL AUDIT
REPORT, 2017

| Food Safety Department<br>Microbiological Food Safety Unit | Pvm/Datum/Date<br>21.7.2017 | Dnro/Dnr/DNo<br>Evira/253/0477/2017 |
|---|---|---|

Jane H. Doherty
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 JANUARY 25 THROUGH FEBRUARY 8, 2017**

The Finnish Food Safety Authority Evira (Evira) understands the findings reported in the Food Safety and Inspection Service (FSIS) draft final report concerning the on-site equivalence verification audit conducted in Finland by FSIS from January 25 through February 8, 2017. During the closing meeting of the audit Evira informed the FSIS auditors about the immediate corrective actions Evira has taken and the action plan set to follow up the detected non-compliances. With the present letter Evira replies to topics presented in the draft final audit report, but not considered by FSIS to represent an immediate threat to public health, and gives some technical comments regarding the information in the draft final audit report.

**Government Oversight: Private Microbiological Laboratories**

According to the draft final audit report the oversight of private microbiological laboratories performing food safety testing of products eligible for export to the United States is inadequate. The frequency at which the Central Competent Authority (CCA) conducts supervisory visits to audit the control of private microbiological laboratories, has been increased for all these laboratories after the 2017 FSIS audit. This is done to further strengthen the oversight of the private microbiological laboratories by the CCA and to ensure the correct functioning of the laboratories internal quality control procedures. The laboratories are checked for and reminded about the importance of the correct functioning of internal quality control procedures at the audits. Methods for

auditing the laboratories will also be further developed by the CCA before the end of 2017.

At the last supervisory visits in June 2017, to the laboratories not audited by FSIS in 2017, the CCA verified the monitoring of temperatures in the incubators. In one of the laboratories an automatic temperature controlling system has been installed after the FSIS audit in 2015. In the other laboratory the analyses will be conducted with incubators with an automatic temperature controlling system before the end of 2017, according to a plan provided by the company. As a short term solution, until the automatic temperature controlling system is taken into use, the laboratory has increased the manual monitoring of incubators to cover also weekends and off days.

At the laboratory audited by FSIS during the 2017 audit, an automatic temperature controlling system for the incubators is going to be in use before the end of 2017, according to a plan provided by the company. Until then the laboratory is following the temperatures manually also on weekends and off days. The CCA will at supervisory visits verify that the new temperature controlling systems have been taken into use, before the end of 2017.

In the laboratory audited by FSIS in 2017 the storage temperature of Rambach agar was changed to 7 ± 1 °C instead of 4 ± 1 °C. To ensure right procedures in storing and shelf life of agars, the laboratory has reviewed the document *#1476 Quality controls at microbiological laboratory* with all laboratory workers. These corrective actions are going to be verified by the CCA on the next supervisory visit.

**Government Sanitation: Equipment Maintenance of Product Contact Surfaces**

The draft final audit report states that the FSIS auditors identified sanitation findings at two audited establishments reflective of the CCA's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations. According to the report several deficiencies were noted on various types of conveyor belts that come into contact with exposed product. According to the Appendix A to the report these findings were however found only in one of the audited establishments. Also during the audit and in the audit exit meeting, the FSIS auditors pointed out conveyor belt deficiencies only in one of the audited establishments.

To address the findings of the FSIS audit the official control of conveyor belts has been further increased in the establishment at which the FSIS auditors found deficiencies concerning equipment maintenance of product contact surfaces, both by the in-plant government officials and by the CCA at supervisory visits. The in-plant inspection personnel have increased the inspection of conveyor belts to be done each working day. Each conveyor belt that comes into direct contact with exposed products or runs above exposed products is now inspected at least once per week and all other conveyor belts are inspected at least every second week. The use of risk based inspection has been more strongly implemented and now the conveyor belts that are

most prone to become worn or broken are inspected each day. Information about which conveyor belts have been inspected is included in the documentation by the official veterinarians (OV). The in-plant inspection personnel have also increased the frequency of follow-up of observed non-compliances.

The CCA has audited the condition of conveyor belts at the establishment at the regular supervisory visit conducted in June 2017, and the conveyor belts were then in good condition. No deficiencies were found in the conveyor belts at that time. The CCA will continue with the increased frequency of supervision of conveyor belts during the audits, until satisfied that the establishment and in-plant government officials can prevent the reoccurrence of equipment maintenance non-compliances of product contact surfaces.

To strengthen the effectiveness of the measures described above the establishment at which the FSIS auditors found deficiencies concerning equipment maintenance of product contact surfaces has by Evira been given an official order on March 13, 2017 based on the *National Food Act 23/2003*. This order states that the establishment has to change meat conveyor belts already when the surface starts to be worn-out and before there is a hole in a conveyor belt, the surface of the conveyor belt is broken or there is a danger of a piece coming off a conveyor belt. The order was reinforced by a penalty payment according to the *National Food Act 23/2003,* that the establishment can be sentenced to pay, if Evira notices that the requirements of the order have not been filled. The order is attached as an annex to this letter.

The establishment concerned has in several ways increased the efforts to control the condition of conveyor belts. The monitoring of conveyor belts has been included as a separate task in the monitoring of SSOP by the foreman, and the results are documented. The conveyor belts are also inspected each day before the start of production and broken conveyor belts are then forbidden to be used until they are repaired. This is also documented. All cutting plant employees have to now immediately report any noticed deficiencies to the person in charge of the line. The maintenance has also been required to prioritize conveyor belt maintenance and illustrated instructions have been prepared for them by the establishment.

**Sanitary Operations – Sanitary Dressing Procedures**

In Finland presence of hair on food products is unacceptable. As a response to the audit finding of hair on carcasses in one of the audited establishments the in-plant government officials and the CCA have both increased the frequency of supervision focused on the appearance of hair on carcasses in the establishment. The in-plant inspection personnel have started to inspect carcasses for hairs in the slaughterhouse and at the cutting plant. 11 carcasses are inspected specifically for hairs by the OVs each week at the cutting plant. At the slaughterhouse carcasses are inspected thoroughly for hairs as part of the post mortem inspection at the side track. The OVs have also instructed the meat inspectors to direct carcasses with hairs to the side

track where they are skinned. Hair removal from the carcasses has been a recurrent discussion topic at weekly meetings between the OVs and the establishment since the FSIS audit.

Evira has started a project which assess carcass cleanliness in most slaughterhouses in Finland and also the slaughterhouse were the FSIS auditors found carcasses with hairs takes part in this project. The project started in May 2017 and will continue for one year. In the project the OVs in the slaughterhouse have to visually inspect at least 60 pig carcasses monthly for ingesta, hairs and other contamination. All observed contamination is documented and these documents will be sent to the CCA.

The CCA has increase the frequency of supervising carcasses for hair at the regular supervisory visits at the establishment concerned. The CCA will continue with the increased frequency of supervision of the carcasses during the audits, until satisfied that the establishment and in-plant government officials can prevent the reoccurrence of the problem.

The establishment concerned has increased the efforts to prevent the occurrence of hair on carcasses. There is now an additional employee on the slaughtering line removing manually hairs from carcasses with a knife. After the audit the establishment has started to change the flaps in the scalding machines more often and the flaps are now changed proactively. Also brushes and whips have been changed and the functioning of burners has been checked and is continuously monitored. The foreman at the slaughterhouse now monitors carcasses for hairs daily and documents the findings.

**CCA Zero-Tolerance Verification**

The FSIS auditors observed that the off line veterinarian at one of the audited establishments did not adequately examine the outer surface of the entire carcass while conducting zero-tolerance verification of the carcass. To address this finding the CCA has checked the performance of zero-tolerance verification on the on-site supervisory visits at both slaughterhouses after the FSIS 2017 audit. At the visit at the slaughterhouse which FSIS audited in 2017, the OV thoroughly rotated the carcasses and adequately examined the surface of the entire carcasses. At the other slaughterhouse the CCA noticed that the OV did not examine the entire carcass while performing zero-tolerance verification, but the OV corrected the performance when noted about the deficiency by the CCA.

After these supervisory visits, written instructions on the correct performance of zero-tolerance verification were sent by the CCA via email to the OVs. In this email the OVs performing zero-tolerance verification were reminded to rotate the carcasses so that all surfaces of the carcasses can be examined when performing zero-tolerance verification and to make sure the entire outer surfaces of each carcass is examined. The OVs were also instructed not to select consecutive carcasses for the verification,

to have enough time to check the whole carcasses properly. The instructions on the performance of zero-tolerance verification in the *Evira Manual 18511/2* were included in the email. The supervisory OVs were also asked to review these instructions with all OVs performing zero-tolerance verification.

The CCA will continue with the increased frequency of supervision of zero-tolerance verification at supervisory visits to slaughterhouses until satisfied that it is correctly performed.

**Technical Comments Regarding the Information in the Draft Final Audit Report**

The *Meat Inspection Act (1470/2011)*, mentioned on pages 3 and 4 and *Statue No. 38/EE/2006* mentioned on pages 6 and 10 in the draft final audit report have been replaced by the *National Decree on Meat Inspection (590/2014)*.

The Act that designates Evira as the CCA for the meat inspection system, as mentioned on pages 3-4 of the report, is the *Finnish Food Act 23/2006*.

On page 4 of the draft final audit report it is mentioned that Evira is headed by the Chief Veterinary Officer (CVO). However the CVO of Finland works for the Ministry of Agriculture and Forestry and Evira is headed by the Director General.

The approval process for food establishments, as mentioned on page 5 of the report, is provided in Sections 13-15 of the *Finnish Food Act 23/2006*.

The Evira manuals for Plants Approved for Exporting to the United States have been renumbered. The manuals *18510/1* and *18511/1* as mentioned on pages 5, 9, 10, 11, 12, 13, 15 and 19 of the report are now numbered *18510/2* and *18511/2* respectively.

The requirement to use government-paid employees for meat inspection tasks as mentioned on page 6 of the report, comes from the Chapter 6 of the *Finnish Food Act (23/2006)*.

The Finnish Meat Research Institute (FMRI) mentioned on page 7 of the draft final audit report has been closed and training courses for OVs are now provided by the CCA and the University of Helsinki.

The handling of condemned animals as mentioned on page 10 of the report is now regulated by the *By-Products Regulation ((EC) No 1069/2009)* and the *National By-Product Act (517/2015)*.

The presence of an OV during post-mortem examination, as mentioned on page 10 of the report, is mandated in Chapter II of Section III of Annex I of *Regulation (EC) 854/2004*.

Food Safety Department
Microbiological Food Safety Unit

Pvm/Datum/Date
21.7.2017

Dnro/Dnr/DNo
Evira/253/0477/2017

The *Finnish Sanitation Guideline No. 662/32/03*, mentioned on page 13 of the report, is no longer in use and it has been replaced by several new guidelines, amongst others an *Evira Guideline on Risk Based Control of Food Establishments 16044/1* and by Guidelines for the Oiva-system.

The *Finnish National Salmonella Regulation No. 20/EEO/2001*, mentioned on page 19 in the draft final audit report has been replaced by the *National Decree on Salmonella control in meat establishments (134/2012)*.

On behalf of Director General,
Director of Food Safety Department

Leena Räsänen

Senior Officer
Export Team, Microbiological Food Safety Unit

Karolina Östman

Annex I: An order given by Evira on 17th March 2017 "Päätös määräyksen antamisesta ja uhkasakon asettamisesta määräykselle".

Evira

PÄÄTÖS

Elintarviketurvallisuusvirasto
Elintarviketurvallisuus

17.3.2017

Evira/249/0477/2017

HKScan Finland Oy
Teollisuuskatu 17
30420 Forssa

**PÄÄTÖS MÄÄRÄYKSEN ANTAMISESTA JA UHKASAKON ASETTAMISESTA MÄÄRÄYKSELLE**

**ASIANOSAINEN**

HKScan Finland Oy
Teollisuuskatu 17
30420 Forssa

**ASIAN TAUSTA**

HKScan Finland Oy:n laitoksella on 14.3.2015 suoritettu USA:n vientiin hyväksytyn laitoksen tarkastus (Evira/79/0477/2015). Tarkastuksella tarkastettiin muun muassa leikkaamon tuotannon aikaista toimintaa. Tarkastusraportin mukaan leikkaamossa alkupaloittelussa havaittiin useissa lihan kuljetinnauhoissa pinnan tai reunan rikkoontumista. Havainnoista tehtiin laitokselle epäkohtaraportti (epäkohtaraportti 2/2015, 4/2015 ja 6/2015).

Laitokselle suoritettiin 9.4.2015 uudelleen tarkastus, jossa todettiin, että leikkaamossa 14.3.2015 tarkastuksella havaitut useat rikkoutuneet ja kuluneet kuljetinnauhat olivat kaikki vaihdettuja ja hyväkuntoisia. Tällä tarkastuksella havaittiin kuitenkin yksi kuljetinnauha, jossa oli repeämä. Laitoksen edustaja määräsi kuljetinnauhan vaihdettavaksi päivän päätteeksi.

Tarkastusraportissa 9.4.2015 todetaan, että ehkäisevänä toimenpiteenä laitos on tarkentanut omavalvontaansa niin, että aamuvalvoja tarkastaa päivittäin muun muassa kuljetinnauhat. Tämän lisäksi aamuvalvojan ohjeeseen oli lisätty vaihtokuntoisen kuljettimen määritelmä. HKScan Finland Oy:n omavalvontasuunnitelman mukaan kuljetin on vaihdettava välittömästi (laitettava käyttökieltoon), jos on vaara, että kuljettimesta irtoaa vierasesineitä ja on vaara, että kuljetin aiheuttaa tuoteturvallisuusriskin. Tämän mukaisesti, jos kuljettimen pinta on kulunut tuotekontaktikohdasta, mutta siitä ei irtoa mitään, kuljetin voidaan vaihtaa tuotannon jälkeen. Rikkonainen reunanauha voidaan omavalvontasuunnitelman mukaan siistiä niin, että kuljetinta ei ole tarvetta vaihtaa, mutta tämä voidaan aikatauluttaa esimerkiksi seuraavaan viikonloppuun.

HKScan Finland Oy:n omavalvontasuunnitelma sisältää myös kuvauksen omavalvontaan kuuluvien rakenteiden tarkastamiseksi. Tämän mukaisesti rakenteiden kunto tarkastetaan viikoittain sekä kerran kuukaudessa tapahtuvilla kierroksilla. Seurannoissa kiinnitetään huomiota muun muassa kuljettimien kuntoon.

Erityisesti kiinnitetään huomiota tuotekontaktipintoihin ja tuotteen yläpuolisiin rakenteisiin. Kuvauksen mukaan kierroksella tehdään myös havaituista puutteista riskiarviointi ja kierroksista raportti. Havaituille puutteille tehdään korjaussuunnitelma, joka pitää sisällään aikataulun.

Tarkastuseläinlääkärit kirjaavat valvonnassa havaitut poikkeamat erilliseen taulukkoon, joka annetaan sähköisesti tiedoksi laitokselle. Tarkastuseläinlääkärin havainnon mukaan 29.9.2016 kinkkulinjan alkupäässä olevassa poikittaisessa nauhassa oli osittain rikkoutuneita keskipalkkeja nauhassa. Huomautuksen jälkeen laitos vaihtoi nauhan uuteen. Tarkastuseläinlääkäri on valvonnassaan huomannut myös 3.11.2016 poikkeaman kuljetinnauhoissa. Tämän mukaisesti alkupaloittelun kinkkulinjan ensimmäisen kuljettimen nauha oli useista paikoista reunasta rikkoontunut. Tarkastuseläinlääkärin huomautuksen jälkeen nauha oli jälleen laitoksella vaihdettu uuteen.

HKScan Finland Oy:n laitoksella on 27.1.2017 suoritettu USA:n vientiin hyväksytyn laitoksen tarkastus, jolloin laitoksella jälleen havaittiin huonokuntoisia kuljetinnauhoja.

Laitoksen omavalvontatoimenpiteistä huolimatta laitoksella on siten tuotannon aikana havaittu tarkastuseläinlääkärin valvonnan ja tarkastusten yhteydessä huonokuntoisia kuljetinnauhoja. Laitoksen toimenpiteet kuljetinnauhojen kunnon valvomiseksi eivät siten ole olleet riittäviä.

**KUULEMINEN**

HKScan Finland Oy:lle varattiin hallintolain (343/2004) 34 §:n mukaisesti tilaisuus tulla kuulluksi 8.2.2017 toimitetulla kuulemiskirjeellä. HKScan Finland Oy on 15.2.2016 toimittanut vastineen kuulemiskirjeeseen.

Vastineessaan HKScan Finland Oy on pyytänyt tarkennuksia koskien Eviran määräystä Evira/249/0477/2017, jonka mukaisesti HKScan Finland Oy:n tulee vaihtaa lihan kuljetinnauha uuteen laitoksen omavalvontasuunnitelman mukaisesti silloin kun kuljetinnauhan pinta alkaa olla kulunut. Edelleen määräyksen mukaisesti kuljetinnauha tulisi kuitenkin vaihtaa uuteen ennen kuin kuljetinnauhassa havaitaan reikiä tai pinnan kulumista.

HKScan Finland Oy on todennut, että tapauksessa, jossa kuljetinpinta on kulunut, omavalvonnassa ohjeistetaan arvioimaan nauhan vaihtotarve vaaran kriittisyyden mukaisesti. Tämän jälkeen määritettäisiin nauhan vaihtoaikataulu.

Vastineen mukaan tapauksessa, jossa nauhaan on tullut reikä tai kuljettimen reuna on rikkoutunut niin, että kuljettimesta lähtee irtoavia osia, on kuljetin vaihdettava välittömästi. HKScan Finland Oy on todennut, että prosessissa, jossa käsitellään luullisia tuotteita, tämä voi ilmetä äkillisesti. Vastineessa todetaan olevan myös mahdollista, että kuljettimen reuna osuu prosessin aikana äkillisesti kuljettimen reunarakenteisiin rikkoen kuljettimen reunan. Näissä tapauksissa laitos ryhtyisi korjaaviin toimenpiteisiin välittömästi vian ilmettyä.

HKScan Finland Oy on pyytänyt Eviralta tarkennuksia antamiinsa määräyksiin mahdollisten äkillisten poikkeustilanteiden varalta.

## PÄÄTÖS

Evira määrää tällä päätöksellä, että HKScan Finland Oy:n tulee vaihtaa lihan kuljetinnauha uuteen laitoksen omavalvontasuunnitelman mukaisesti silloin kun kuljetinnauhan pinta alkaa olla kulunut ja ennen kuin on vaara, että kuljettimesta irtoaa vierasesineitä. Kuljetinnauha tulee vaihtaa uuteen ennen kuin kuljetinnauhassa havaitaan reikiä, pinnan rikkoontumista tai vierasesineiden irtoamista. Jos kuljetinnauha on kulunut, nauhan vaihtotarve tulee määritellä vaaran kriittisyyden mukaisesti ja kirjata huomio sekä nauhan vaihtoajankohta ylös. Kulunut kuljetinnauha tulee vaihtaa kuitenkin viimeistään päivän tuotannon jälkeen.

Jos kuljetinnauha rikkoontuu äkillisesti, on nauha vaihdettava välittömästi laitoksen toimesta tai laitettava kyseinen linja käyttökieltoon laitoksen toimesta ennen kuin tarkastuseläinlääkäri puuttuu asiaan.

## PERUSTELUT

Yleisen elintarvikehygienia-asetuksen (EY) N:o 852/2004 liitteen II luvun II f kohdan mukaisesti elintarvikkeiden käsittelyalueiden pinnat (mukaan lukien laitteiden pinnat) ja erityisesti elintarvikkeiden kanssa kosketuksiin joutuvat pinnat on pidettävä hyvässä kunnossa, ja niiden on oltava helposti puhdistettavia ja tarvittaessa desinfioitavia. Tämä edellyttää sileiden, pestävien, ruostumattomien ja myrkyttömien materiaalien käyttöä, ellei elintarvikealan toimija pysty osoittamaan toimivaltaisille viranomaisille, että muut käytetyt materiaalit ovat soveltuvia.

Yleisen elintarvikehygienia-asetuksen (EY) N:o 852/2004 liitteen II luvun V mukaan kaikki elintarvikkeiden kanssa kosketuksiin joutuvat esineet, välineet ja laitteet on puhdistettava tehokkaasti ja tarvittaessa desinfioitava. Puhdistus ja desinfiointi on suoritettava riittävän usein saastumisriskin välttämiseksi. Ne on rakennettava siten, valmistettava sellaisista materiaaleista, pidettävä sellaisessa järjestyksessä ja huollettava siten, että saastumisriski jää mahdollisimman pieneksi.

USA:n vientiin hyväksytyn laitoksen tarkastuskäynneillä 14.3.2015 ja 27.1.2017 on havaittu lihan kuljetinnauhoissa pinnan tai reunan rikkoontumista. Myös tarkastuseläinlääkäri on toistuvasti joutunut huomauttamaan huonokuntoisista kuljetinnauhoista. Kuljetinnauhojen kunto ei siten ole täyttänyt yleisen elintarvikehygienia-asetuksen (EY) N:o 852/2004 asettamia elintarvikehygieenisiä vaatimuksia. Kuljetinnauha tulee pitää puhtaana ja tarvittaessa huonokuntoinen kuljetinnauha tulee vaihtaa uuteen elintarvikkeen terveys- ja saastumisvaaran estämiseksi. Laitoksen toiminnassa ei tule käyttää kuljetinnauhoja, jotka ovat pinnasta tai reunoilta rikkoutuneita.

Elintarvikelain (23/2006) 16 §:n mukaan elintarvikealan toimijan on noudatettava kaikessa toiminnassaan riittävää huolellisuutta, jotta elintarvike, elintarvikehuoneisto ja alkutuotantopaikka sekä elintarvikkeen säilytys-, kuljetus- ja käsittelyolosuhteet täyttävät tämän lain mukaiset vaatimukset.

Elintarvikelain 19 §:n mukaisesti elintarvikealan toimijalla on oltava riittävät ja oikeat tiedot tuottamastaan, jalostamastaan ja jakelemastaan elintarvikkeesta. Elintarvikealan toimijan on tunnettava elintarvikkeeseen ja sen käsittelyyn liittyvät terveysvaarat sekä elintarviketurvallisuuden ja muiden tämän lain 2 luvun mukaisten vaatimusten kannalta kriittiset kohdat toiminnassaan.

Elintarvikelain 20 §:n mukaisesti elintarvikealan toimijan on laadittava kirjallinen suunnitelma omavalvonnasta (omavalvontasuunnitelma), noudatettava sitä ja pidettävä sen toteuttamisesta kirjaa. Omavalvontasuunnitelmassa tulee kuvata 19 §:ssä tarkoitetut kriittiset kohdat ja niihin liittyvien riskien hallinta.

HKScan Finland Oy on laitokselle 14.3.2015 suoritetun tarkastuksen jälkeen omavalvontasuunnitelmassaan kuvannut toimenpiteet kuljetinnauhojen kuntoisuuden valvomiseksi. Laitoksen tulisi siten omavalvonnassaan havaita kuluneet kuljetinnauhat ja vaihtaa ne uusiin. Laitoksen omavalvontatoimenpiteet eivät kuitenkaan ole olleet riittäviä, sillä tarkastuseläinlääkäri on toistuvasti joutunut huomauttamaan laitosta kuljetinnauhojen huonokuntoisuudesta.

Elintarvikelain 55 §:n mukaan valvontaviranomainen voi määrätä epäkohdan poistettavaksi, jos elintarvike tai siitä annetut tiedot, elintarvikkeen tuotanto-, jalostus- tai jakeluvaihe, elintarvikehuoneisto, alkutuotantopaikka tai niissä harjoitettava toiminta voivat aiheuttaa terveysvaaraa, vaarantaa elintarvikkeesta annettujen tietojen oikeellisuuden tai riittävyyden, johtaa kuluttajaa harhaan tai ovat muutoin elintarvikemääräysten vastaisia.

HKScan Finland Oy ei siten ole noudattanut yleisen elintarvikehygienia-asetuksen N:o 852/2004 mukaisia vaatimuksia, joiden mukaisesti elintarvikkeen kanssa kosketuksiin joutuvat pinnat on pidettävä hyvässä kunnossa. Tämän johdosta Evira antaa asiassa edellä määrätyn päätöksen.

## PÄÄTÖS UHKASAKON ASETTAMISESTA PÄÄVELVOITTEEN TEHOSTEEKSI

Määräyksen tehosteeksi valvontaviranomainen voi elintarvikelain 68 §:n perusteella ja uhkasakkolain (1113/1990) mukaisesti asettaa uhkasakon määräyksessä mainitun päävelvoitteen tehosteeksi.

Evira asettaa tällä päätöksellä määräykselle uhkasakon ja määrää uhkasakon suuruudeksi päävelvoitteen osalta **kymmenentuhatta (10.000) euroa.** Määräykselle asetettu uhkasakko on voimassa **yhden (1) vuoden** tämän päätöksen antopäivästä lukien.

Uhkasakon asettaminen tarkoittaa sitä, että päävelvoitteen tehosteeksi asetettu uhkasakko voidaan tuomita maksettavaksi, mikäli uhkasakon asettanut valvontaviranomainen havaitsee, ettei määräyksessä asetettuja velvoitteita noudateta. Mikäli HKScan Finland Oy noudattaa viranomaisen määräystä, ei uhkasakkoa tuomita maksuun, eikä uhkasakon asettamisesta siten koidu HKScan Finland Oy:n toimintaan mitään ylimääräistä huomioon otettavaa.

Uhkasakkolain 8 §:n mukaan uhkasakon suuruutta harkittaessa on otettava huomioon päävelvoitteen laatu ja laajuus, velvoitetun maksukyky ja muut asiaan vaikuttavat seikat.

Koska uhkasakon asettamisen tarkoituksena on saada velvoitettu noudattamaan päävelvoitetta, on uhkasakon suuruus harkittava siten, että sen voidaan olettaa johtavan päävelvoitteen täyttämiseen. Uhkasakon käytön tarkoituksena on lakisääteisten velvoitteiden ja viranomaisten päätösten noudattamisen turvaaminen.

Uhkasakon suuruutta harkittaessa on ensisijaisesti otettu huomioon päävelvoitteen laatu, sillä määräyksessä asetetuilla velvoitteilla turvataan elintarvikkeiden

turvallisuutta ja elintarvikkeeksi soveltuvuutta Euroopan unionin ja neuvoston asetuksen (EY) N:o 178/2002 14 artiklan mukaisesti. Kyse on myös velvoitteista, joilla turvataan ihmisten terveyttä ja kuluttajien luottamusta elintarvikkeiden turvallisuuteen.

Euroopan parlamentin ja neuvoston asetuksen (EY) N:o 882/2004 artiklan 54 mukaan kun toimivaltainen viranomainen toteaa, että säännöksiä ei noudateta, sen on toteutettava toimenpiteitä sen varmistamiseksi, että toimija korjaa tilanteen. Päättäessään toimenpiteistä toimivaltaisen viranomaisen on otettava huomioon säännösten noudattamatta jättämisen luonne sekä se, missä määrin kyseinen toimija on aiemmin jättänyt noudattamatta säännöksiä.

Uhkasakon suuruutta harkittaessa on otettu huomioon myös toimijan aikaisempi sääntöjen noudattamatta jättäminen. Uhkasakon asettamista ja suuruutta arvioitaessa on huomioitu se, että laitosta on jouduttu useampaan otteeseen huomauttamaan lihan kuljetinnauhojen pintojen ja reunojen rikkoontumisesta. Vaikka laitos on tarkastuseläinlääkärin huomauttamisen jälkeen vaihtanut huonokuntoiset kuljetinnauhat uusiin, on laiminlyönti ilmennyt aina uudelleen, minkä lisäksi laitoksen omavalvonta on ollut riittämätöntä kuljetinnauhojen kunnon valvomiseksi.

## SOVELLETUT SÄÄDÖKSET

Euroopan parlamentin ja neuvoston asetus (EY) N:o 882/2004 rehu- ja elintarvikelainsäädännön sekä eläinten terveyttä ja hyvinvointia koskevien sääntöjen mukaisuuden varmistamiseksi suoritetusta virallisesta valvonnasta
Euroopan parlamentin ja neuvoston asetus (EY) N:o 178/2002 elintarvikelainsäädäntöä koskevista yleisistä periaatteista ja vaatimuksista, Euroopan elintarvikeviranomaisen perustamisesta sekä elintarvikkeiden turvallisuuteen liittyvistä menettelyistä
Euroopan parlamentin ja neuvoston asetus (EY) N:o 852/2004 elintarvikehygieniasta
Elintarvikelaki (23/2006)
Uhkasakkolaki (1113/1990)
Hallintolaki (434/2003)

## PÄÄTÖKSEN TÄYTÄNTÖÖNPANO

Tätä päätöstä on noudatettava mahdollisesta muutoksenhausta huolimatta, ellei muutoksenhakuviranomainen toisin määrää.

## MUUTOKSENHAKU

Tähän päätökseen saa hakea muutosta valittamalla Hämeenlinnan hallinto-oikeuteen liitteenä olevasta valitusosoituksesta ilmenevällä tavalla.

Leena Räsänen
Johtaja

Pauliina Pelto-Piri
Lakimies

**Lisätiedot**

Lisätietoja asiassa antaa lakimies Pauliina Pelto-Piri, p. 029 530 4321 (pauliina.pelto-piri@evira.fi)

JAKELU Saantitodistuksella toimijalle

TIEDOKSI Tarkastuseläinlääkäri Timo Laita
Aluejohtaja Eeva Japisson

LIITTEET Valitusosoitus

# VALITUSOSOITUS

Tähän päätökseen tyytymätön saa hakea siihen muutosta valittamalla **Hämeenlinnan hallinto-oikeuteen**. Valitus on tehtävä kirjallisesti.

**Valitusaika**

Valitus on tehtävä **30 päivän kuluessa päätöksen tiedoksisaantipäivästä**. Ajan laskeminen alkaa tiedoksisaantipäivää seuraavasta päivästä.

Tiedoksisaantipäivä lasketaan seuraavasti:
- Jos päätös on luovutettu asianosaiselle tai tämän edustajalle tiedoksisaantipäivä ilmenee tiedoksiannosta laaditusta kirjallisesta todistuksesta.
- Jos päätös on lähetetty postitse saantitodistusta vastaan, tiedoksisaantipäivä ilmenee saantitodistuksesta.
- Jos päätös on postitettu tavallisena kirjeenä sen katsotaan tulleen tiedoksi seitsemäntenä päivänä postituspäivästä, jollei muuta ilmene.
- Jos päätös on annettu tiedoksi muulle henkilölle kuin asianosaiselle tai tämän edustajalle (sijaistiedoksianto), katsotaan asianosaisen saaneen päätöksen tiedoksi kolmantena päivänä sijaistiedoksiantoa koskevan tiedoksiantotodistuksen osoittamasta päivästä.
- Jos päätös on annettu asianosaisen suostumuksella tiedoksi sähköisenä viestinä sähköpostilla, katsotaan asianosaisen saaneen sen tiedoksi kolmantena päivänä viestin lähettämisestä, jollei muuta näytetä.

**Valituskirjelmän sisältö ja allekirjoittaminen**

Valituskirjelmässä, joka osoitetaan **Hämeenlinnan hallinto-oikeudelle**, on ilmoitettava seuraavat asiat:
- valittajan nimi ja kotikunta
- postiosoite ja puhelinnumero, joihin asiaa koskevat ilmoitukset valittajalle voidaan toimittaa
- päätös, johon muutosta haetaan
- miltä kohdin päätökseen haetaan muutosta, mitä muutoksia siihen vaaditaan tehtäväksi ja millä perusteilla muutosta vaaditaan.

Valittajan, laillisen edustajan tai asiamiehen on allekirjoitettava valituskirjelmä. Jos valittajan puhevaltaa käyttää hänen laillinen edustajansa tai asiamiehensä taikka jos valituksen laatijana on joku muu henkilö, valituskirjelmässä on ilmoitettava myös tämän nimi ja kotikunta.

**Valituskirjelmän liitteet**

Valituskirjelmään on liitettävä:
- valituksenalainen päätös alkuperäisenä tai jäljennöksenä
- tiedoksisaantitodistus tai muu selvitys valitusajan alkamisen ajankohdasta
- asiamiehen valtakirja, mikäli asiamiehenä ei toimi asianajaja tai yleinen oikeusavustaja
- mahdolliset asiakirjat, joihin valittaja vetoaa vaatimuksensa tueksi, jollei niitä ole jo aikaisemmin toimitettu viranomaiselle.

**Valituskirjelmän toimittaminen**

Valituskirjelmä on toimitettava valitusajassa **Hämeenlinnan hallinto-oikeudelle**. Valituksen voi toimittaa henkilökohtaisesti, postitse maksettuna postilähetyksenä, sähköisellä tiedonsiirtomenetelmällä taikka asiamiestä tai lähettiä käyttäen. Valituskirjelmän lähettäminen postitse tai sähköisesti tapahtuu lähettäjän omalla vastuulla. Valituksen on saavuttava viranomaiselle virka-aikana ennen 30 päivän valitusajan päättymistä, jotta valitus voidaan tutkia. Jos valitusajan viimeinen päivä on pyhäpäivä, lauantai, itsenäisyyspäivä, vapunpäivä, jouluaatto tai juhannusaatto, valitusaika jatkuu kuitenkin vielä seuraavan arkipäivän virka-ajan päättymiseen. Oikeuslaitoksen internetsivuilla on tarkemmat ohjeet asiakirjojen toimittamisesta sähköisesti: http://www.oikeus.fi.

**Oikeudenkäyntimaksu**

Muutoksenhakuasian käsittelystä hallinto-oikeudessa peritään 250 euron suuruinen oikeudenkäyntimaksu. Muutoksenhakija on maksun suorittamisesta vapaa, jos hallinto-oikeus muuttaa alemman viranomaisen päätöstä muutoksenhakijan eduksi. (Tuomioistuinmaksulaki (1455/2015).

**Yhteystiedot**

Hämeenlinnan hallinto-oikeus

| | |
|---|---|
| Osoite: | Raatihuoneenkatu 1<br>13100 HÄMEENLINNA |
| Puhelinvaihde: | 029 56 42200 |
| Telefax: | 029 56 42269 |
| Sähköposti: | hameenlinna.hao@oikeus.fi |
| Virka-aika | klo 8.00 - 16.15 |

HKScan Finland Oy
Teollisuuskatu 17
30420 Forssa

**DECISION ON GIVING AN ORDER AND SETTING A PENALTY PAYMENT TO THE ORDER**

**PARTY**

HKScan Finland Oy
Teollisuuskatu 17
30420 Forssa

**BACKGROUND**

The HKScan Finland Oy factory was verified by the US Export Control Authority (Evira/79/0477/2015) on March 14, 2015. Among other things, the inspection checked the operation in the cutting room during the time of production. According to the inspection report, a number of breakages on the surface or edges of the meat conveyor belts were found in the cutting plant. The findings were part of the grievance reports (report in 2/2015, 4/2015 and 6/2015).

The plant was re-inspected on April 9, 2015 and it was observed that the many broken and worn-out conveyor belts identified on March 14, 2015 were all replaced and in good condition. However, this inspection revealed one conveyor belt with a breakage. The representative of the organization ordered the conveyor belt to be replaced by the end of the day.

The audit report dated April 9, 2015 indicates, as a preventative measure, that the section has clarified its own control policy, so that the inspector checks the conveyor belt daily. In addition, a definition of a replaceable conveyor belt was added to the morning supervisor's manual. According to HKScan Finland Oy's internal control plan, the conveyor must be replaced immediately (and its use banned), if there is danger of invasive objects falling off the conveyor and it causes a product safety risk. In view of this, if the conveyor surface is worn at the product contact point but nothing is falling off, the conveyor can be replaced after production. According to the internal control plan, the broken edge of a belt can be tidied so that the conveyor does not require replacement promptly and the replacement can be scheduled for the next weekend.

HKScan Finland Oy's internal control plan also includes a description for internal monitoring structural checks. According to this, the condition of structure is checked on a weekly basis and monthly rounds. For example, the company shall take notice of the conveyors' condition.

Special attention shall be paid to the surface in contact with the product and the structures above the product. According to the description, a risk assessment of observed deficiencies shall be made on the rounds. A repair plan including a timeline will be made for the detected deficiencies.

In the controls, veterinary inspectors detected deficiencies on a separate table which is given to the institution electronically. According to the veterinary inspection finding dated 9/29/2016, the central bars at the beginning of the main transverse belt were partially broken. After this was noted, the plant replaced them with a new belt. The official veterinarian also noticed a discrepancy in the conveyor belts under their supervision on 11/3/2016. In view of this, several edges were found broken on the first conveyor belt of the ham products' initial chopping. With an inspection by the veterinarian, the belt was replaced with a new one.

The Plant of HKScan Ltd. (Finland) was verified by the US Export Control Authority on January 27, 2017, when conveyor belts in poor shape were found again.

Despite internal measures, the internal control department identified damaged conveyor belts during production under the veterinarian's supervision and controls. The measures the plant took to control the condition of the conveyor belts were insufficient.

**HEARING**

In accordance with Section 34 of the Administrative Procedure Act (343/2004), HKScan Ltd. (Finland) was given an opportunity to be heard by a formal letter of notice dated February 8, 2017. HKScan Ltd. (Finland) gave a reply with the formal letter of notice dated February 15, 2016.

In the reply, HKScan Ltd. (Finland) requested clarification regarding Evira/249/0477/2017, with which they shall replace the conveyor belt wherein the surface starts to wear out with a new one based on the internal control plan. In addition, the conveyor belt shall be replaced before a hole or worn surface is observed there.

HKScan Ltd. (Finland) has made a decision and in case the conveyor surface collapses, there shall be an internal control plan guided to estimate the need of a replacement based on hazard standards. Thereafter, the replacement schedule would be established.

In case of a defective puncture visible to the belt or its edge being broken, resulting it to loosen up, the conveyor belt shall be replaced without reasoning. HKScan Ltd. (Finland) indicated that this may occur suddenly in a process that handles products with bones. In response, it is also possible, during the process, that the edge of the conveyor belt impacts the edge of the structure suddenly, damaging the edge and structure. In such cases, the company shall take corrective actions after detecting the defect.

HKScan Ltd. (Finland) has asked the Finnish Food Safety Authority for clarification on its support for a contingency plan.

**DECISION**

The Finnish Food Safety Authority indicates that HKScan Ltd. (Finland) has to replace the meat conveyor belt with a new one in accordance with the internal control plan when the surface of the conveyor belt starts to collapse and there is a risk of foreign object's loosening from the conveyor. The conveyor belt shall be replaced before discovering holes, defective surface or detachment of foreign objects. If the conveyor belt collapses, it shall be replaced pursuant to the hazard standards and note that the deadline of replacement is overdue. However, the worn conveyor belt shall be replaced at the end of production.

If the conveyor belt breaks acutely, it must be replaced by the company or banned for use any longer before the veterinarian executes inspection.

**REASONING**

Based on Chapter II of Annex II of Regulation No. 852/2004: General Food Hygiene Regulation (EC), the surface of food processing zone (included that of the equipment), in particular the surfaces in contact with the foodstuffs, shall be kept in good condition and be easily cleanable, if necessary, it shall be disinfected. A smooth, liquid, non-corrosive and non-toxic material shall be used, unless the operator can demonstrate it to the competent authorities that other materials used are applicable.

Based on Chapter V of Annex II of the General Food Hygiene Regulation (EC) No. 852/2004, all articles, equipment and objects intended to come into contact with foodstuffs must be effectively cleaned and, if necessary, disinfected. Cleaning processes and disinfections must be carried out sufficiently to eliminate the risk of contamination. They must be constructed, kept in good order and maintained in such ways as of such materials to minimize the risk of contamination.

During the inspections by the US Export Control Authority on March 14, 2015 and January 27, 2017, breakages were found on the surface or edge of meat conveyor belts. A male official veterinarian inspector has repeatedly pointed out the ailing conveyor belts. The condition of the conveyor belt thus was not in line with the food hygiene requirements stipulated by the General Food Hygiene Regulation (EC) No. 852/2004. The conveyor belt shall be clean and, if necessary, defective conveyor belts shall be replaced with new ones to avoid risk of food sanitation and contamination. Do not use conveyor belts wherein the surface or edge is broken.

In accordance with Section 16 of the Food Act (23/2006), operators in the food industry shall look out for everything in all activities as largely as they can, so that food, workplace, primary production line, food storage, transportation and handling conditions conform to the requirements of the Food Act.

In accordance with Section 19 of the Food Act, operators in the food industry shall have sufficient and accurate knowledge and information of the food they produce, refine and distribute. The Contractor must be aware of the health risk associated with food and treatment as well as critical food safety and other requirements set forth in Chapter 2 of this Act.

In accordance with Article 20 of the Food Act, contractors in the food industry must prepare a written internal control plan, make a follow up and keep a record of performance. The internal control plan shall describe critical points specified in Section 19 and the related risk management.

HKScan Ltd. (Finland) has described the procedures for supervising the fitness of conveyor bands in its internal control plan following an inspection on March 14, 2015. Therefore, the plant should detect worn conveyor belts in the internal control plan and replace them with new ones. However, the internal control measures have not been sufficient, since the inspector must point out defective conveyor belts repeatedly.

According to Section 55 of the Food Act, the Authority may order a grievance to be removed if the food or information provided, the production, process or distribution of food, workplace, main production line or process of production pose health risk, endanger correctness or disproportionate nature of food information, misleading the consumer or breach the Food Act.

HKScan Ltd. (Finland) therefore does not conform to the requirements of the General Food Hygiene Regulation 852/2004, which provides that the surface where food makes a contact shall be kept in good condition. As a result, the Finnish Food Safety Authority gives clear instruction of specific policy or rules determined by the decision hereof.

## THE DECISION OF SETTING A PENALTY PAYMENT TO ENFORCE THE PRIMARY OBLIGATION

The Authority may, in accordance with Section 68 of the Food Act, and the Penalty Act (1113/1990), decide to impose a periodic penalty payment to enforce the order of the principal obligation.

The Finnish Food Safety Authority imposes a penalty payment and fine based on **Ten thousand (10,000) euros.** The penalty payment provision stipulated is valid for **one (1) year** (including the day the order was issued).

This penalty payment is set due to a primary obligation not met and the National Surveillance Authority finds that these obligations imposed are not satisfied and a penalty payment is to be done. If HKScan Ltd. (Finland) conforms to the regulation of the authority, then, there shall be no penalty payment imposed. There shall also be nothing further to take into account in HKScan Finland Oy's business activities.

According to Section 8, to determine the amount of the penalty, factors to be taken into account, but not limited to, are the quality and to which degree the obligation has not been met.

Since the purpose of imposing a periodic penalty is to comply with the paying obligation, the amount of the penalty shall be considered in such a way that it may expect to satisfy the primary obligations. The purpose of the penalty is to ensure compliance with the legal obligations and the regulation stipulated by the authorities.

The level of penalty shall be depending on the quality of the primary obligation, which was stipulated by Finnish Food Safety Authority in accordance with Article 14 of Regulation (EC) No. 178/2002 of the European Parliament and the Council.

It is also an obligation to safeguard human health and consumers' trust in food safety.

In accordance with Article 54 of Regulation (EC) No 882/2004 of the European Parliament and the Council, the competent authority finds that in the situation of provisions which are not complied with, several steps shall be taken to ensure that the operator remedies the situation. When the competent authority adopts the measures, it shall take into account the nature of the measure and to which degree and extent has the operator complied with regulations before.

The amount of the penalty shall depend on the history of the operator's non-compliance in the past. In the assessment of the amount of penalty, it has been considered that the plant has been notified of breakage of the surface of meat conveyor belts and edges several times. Even though the company has replaced defective conveyor belts after they were discovered during the inspection, the company has always been neglected of, and internal supervisions have been insufficient to control the condition of the conveyor belts.

**APPLIED REGULATIONS**

Regulation (EC) No. 882/2004 of the European Parliament and the Council regarding official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Food Act (23/2006)

Penalty Law (1113/1990)

Administrative Procedure Act (434/2003)

**WARRANTY PERIOD**

Responsibilities and duties shall be met regardless of a potential appeal, unless otherwise agreed by the Appellate authority.

**APPEAL**

This decision may be appealed to the Administrative Court of Hämeenlinna in the manner indicated in the Annex.

Leena Rasanen,
Director

Pauliina Pelto-Piri
Attorney

**ADDITIONAL INFORMATION**

For more information, please contact Pauliina Pelto-Piri, Esq., Tel.: 029 530 4321 (pauliina.pelto-piri@evira.fi)

| | |
|---|---|
| DISTRIBUTION | Acknowledgement of receipt from the contractor |
| INFORMATION | Official Veterinarian Timo Laita<br>Regional Director Eeva Japisson |
| ATTACHMENT | Appeal Instructions |

# APPEAL INSTRUCTIONS

You may seek an appeal to the **Hämeenlinna Administrative Court.** The complaint must be filed in writing.

**The period of appeal**

The complaint has to be made **within 30 days of the service of the decision.** The days are counted starting on the following day after the filing.

The amount of dues payable is calculated as follows:

- If the decision has been handed over to the opposite party or to the team representative, the notice period is shown on the written Certificate of Testimony.
- If the decision has been sent by a mail with acknowledgment of receipt, the Delivery Date is shown on the receipt.
- If the letter is marked as an ordinary letter, it will be deemed to be served on the seventh day of the mailing date, unless otherwise stated.
- If the message was delivered to a person other than a party or a representative of the team (a memorandum), the receiving party shall be deemed to have been informed by the third party of the attestation certificate with alternative notice.
- If the person has been informed with the consent given by the party specified in the message, the party shall be deemed to have been served by the third party in the acknowledgment, unless otherwise specified.

**Contents of the Appeal and Signature**

In the appeal letter to be sent over to **Administrative Court of Hämeenlinna,** the following points must be specified:

- The name and domicile of the appellant
- The postal address and phone number of the appellant where announcements regarding the proceedings can be delivered to.
- In case of a change is sought on the complaint, the point to be changed and where the change should be done must be specified.

The appellant, legal representative or the agent must put their signatures on the appeal. If the appellant is called to execute it by his/her legal representative or agent, or if the complaint is made by another person, the said appeal shall be put into the pleadings with name and county of residence.

**Annexes to the appeal**

The appeal file is attached to:

- The petitioner's first petition of compliant or petitioner's letter of formal notice or other evidence showing the period for the appeal's beginning.
- General power of attorney if the agent is not a lawyer or public legal aid.
- Any documents on which the appellant relies in support of the request, unless it has not been submitted to the authorities.

**Submission of the appeal**

Appeals must be filed to the **Administrative Court of Hämeenlinna.** Complaints may be submitted individually by mail, a prepaid postal mail, any means of communication and by any affidavit or messenger. Written complaints by mail or electronic means are the sender's own responsibility. The complaint must be delivered to the authority during office hours within 30 days so that the complaint can be investigated. If the last day of the appeal period is a public holiday, Saturday, Independence Day, Labor Day, Christmas Eve or Midsummer Night, however, the appeal period will continue until the next business day. The website of the Judiciary Department has more detailed instructions on how to submit documents: http://www.oikeus.fi.

**Court fee**

The appeal to the Administrative Court for a lawsuit is 250 Euros. The appellant has no need to pay it if the Administrative Court modifies the ruling of the lower authority in favor of the appellant. (Court Fee Act (1455)/2015).

**Contact**

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| Address of Hämeenlinna Administrative Court: | Raatihuoneenkatu 1<br>I 3 I00 HAMEENLINNA |
| Telephone exchange: | 029 56 42200 |
| Telefax: | 029 56 42269 |
| Email: | Hameenlinna.hao@oikeus.fi |
| Office hours | From 8.00 to 16.15 |