USDA
United States Department of Agriculture

JUN 1 0 2013

Dr. Eeva-Riitta Wirta
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FINLAND

Dear Dr. Wirta:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Finland's meat inspection system from June 5 through June 20, 2012. Enclosed is a copy of the final audit report. The comments received from the government of Finland are included as an attachment to the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

JUN 1 0 2013

FINAL REPORT OF AN AUDIT CONDUCTED IN

FINLAND

JUNE 5 THROUGH JUNE 20, 2012

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This audit report describes the outcome of the on-site audit of Finland's meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from June 5 through June 20, 2012.

This was a routine on-going equivalence verification audit. The audit objective was to ensure that Finland continues to maintain a food safety inspection system for meat slaughter and processing equivalent to that of the United States, with the resultant capacity to produce products that are safe, wholesome, and properly labeled. In the period from January 1 to December 31, 2011, Finland exported 1,985,379 pounds of raw pork products to the United States. There has been no U.S.'s port-of-entry (POE) violation since FSIS' previous routine audit of Finland's food safety and inspection system in 2009.

During this audit, FSIS reviewed and verified the information provided by the Central Competent Authority (CCA) in the Self Reporting Tool (SRT). The audit scope included one central and three local inspection offices; three swine slaughter establishments; one private microbiology laboratory; and one government residue laboratory. Determinations concerning the effectiveness of Finland's meat inspection system were focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

FSIS determined that the CCA maintains the legal authority and the responsibility to enforce all applicable laws and regulations governing Finland and third-country requirements. The FSIS auditor verified that all prior systemic findings from previous FSIS audit were appropriately addressed and corrected. The audit revealed improvement in all areas of Finland's meat inspection system, and there was no systemic non-compliances reported.

The audit outcome demonstrated that the CCA is able to provide sufficient oversight and to meet the principal requirements for all six equivalence components. The audit concluded that Finland maintains a food safety inspection system for meat slaughter and processing equivalent to that of the United States.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Finnish Food Safety Authority)
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
E. coli	*Escherichia coli*
EVIRA	Finnish Food Safety Authority (CCA)
FINAS	Finnish Accreditation Service
FSIS	Food Safety and Inspection Service
MIU	Meat Inspection Unit
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
Salmonella	*Salmonella* species
SO	Senior Officer
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U.S.	The United States of America
VO	Veterinary Officer

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Finland's meat inspection system from June 5 through June 20, 2012.

The audit began with an entrance meeting held on June 5, 2012, in Helsinki with the participation of representatives from the Central Competent Authority (CCA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS). The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA.

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Finland's food safety system governing meat inspection continues to be equivalent to that of the United States of America (U.S.), with the resultant capability to produce and export products which are safe, wholesome, unadulterated, and properly labeled.

In pursuit of this objective, FSIS conducted an analysis of information provided by Finland in the FSIS document entitled Self Reporting Tool (SRT-2009 version), U.S.'s port-of-entry (POE) testing results, other data collected by FSIS and findings reported from on-site audits conducted in the last three years, prior to conducting this audit.

FSIS determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The administrative functions of the system were reviewed at the CCA headquarters in Helsinki and three local inspection offices. During the review, the FSIS auditor evaluated the implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended.

The review of the administrative functions of the local inspection offices was conducted as part of the establishment review. Three slaughter establishments were reviewed. During the establishments' review, attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, and how the CCA provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

One private microbiology laboratory and one government chemical residue laboratory were audited to verify the CCA's ability to provide adequate technical support to its inspection system.

Sectors Visited During the Audit		No. Sites	Locations
Competent Authority Offices	Central	1	• EVIRA Headquarters office in Helsinki
	Local offices located at eligible establishments	3	• Nurmo • Forssa • Mellila
Private Microbiological Laboratory		1	• HK Ruokatalo Oy in Forssa
Government Residue Laboratory		1	• The Chemical and Toxicology Research Unit in Helsinki
Swine Slaughter Establishments		3	• Est. 18, HK Ruokatalo Oy (Forssa) • Est. 22, Atria Oyj (Nurmo) • Est. 85, HK Ruokatalo (Mellila)

3. LEGAL BASIS FOR THE AUDIT

The audit was conducted under the specific provisions of the United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with European Commission (EC) Regulations 852; 853; 854; 882; 178; 20723; Council Directives 96-22 and 96-23 were assessed.

The audit standards included all applicable legislation and procedures determined to be equivalent by FSIS. Finland has equivalence determinations in place for the following:

- The CCA may allow either establishment or government employees, who are fully trained, 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 EU exporting countries.
- The use of an alternative laboratory testing method ISO 6579; 2002 (modified) for *Salmonella.* In addition, FSIS has granted Finland an equivalence determination allowing the use of methods ISO 6579:1993 and NMKL 71 (dated 1999) for *Salmonella.*
- The use of methods NMKL 147:1993 for generic *E. coli,* and NMKL 144(dated 2005) for *Enterobacteriaceae.*
- The use of private laboratories for the analysis of official samples.

4. BACKGROUND

Finland is eligible to export raw and processed (processed with kill steps sufficient to inactivate bacteria and viruses) pork meat products to the U.S. Currently, Finland only exports raw products to the U.S. Finland exported 1,985,379 pounds of raw pork products in 2011. A total

of 1,116,491 pounds were re-inspected by FSIS at POE in which 120 pounds were rejected due to transportation damage.

FSIS' previous routine audit of Finland's food safety and inspection system was conducted in August 2009. The audit report cited weaknesses in the implementation of the European Union (EU) and FSIS requirements concerning Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), ante-mortem inspection activities, and humane handling and slaughter which resulted in the CCA initiating two enforcement actions (Notice of Intend to Delist or NOID) in two of the three establishments audited. The corrective actions proffered by the CCA, in response to FSIS findings, were reviewed and found to be acceptable by FSIS. As the result, the 2009 FSIS audit concluded that Finland had a food safety inspection system equivalent to that of the United States.

During the current on-site audit, the auditor's review of the CCA's corrective action verification documents indicated that the CCA has a system in place that addresses the effectiveness of the correction of deficiencies identified in 2009 through the documentation, implementation, verification and the analysis of the corrective actions and preventive measures.

The FSIS final audit reports for Finland's meat inspection system are available on the FSIS' website at:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. The auditor verified that the inspection system was organized and administered by the national government of Finland and provided standards equivalent to those of the Federal system of meat inspection in the United States (U.S.). Finland's food safety organization begins with the Ministry of Agriculture and Forestry (MAF). MAF is responsible for the general planning and supervision of food and veterinary controls. The Finnish Food Safety Authority (EVIRA) operates under the auspices of MAF and is the CCA responsible for directing, planning, steering and carrying out food safety, animal health and welfare controls.

EVIRA consists of three departments:

1) Control Department which is in charge of Animal Health and Welfare, Food Hygiene, and Meat Inspection
2) Research and Laboratory Department which is in charge of Chemistry and Toxicology, Food Microbiology, Risk Assessment, Veterinary Bacteriology and Virology, and Pathology
3) Administrative Department which is in charge of Planning, Communications, Human Resources, and Legal Affairs

The Meat Inspection Unit (MIU), a unit under the Control Department, is responsible for meat inspection of U.S. certified establishments. The MIU is managed by the Head of the unit who is appointed by EVIRA's Chief Veterinary Officer (CVO). The MIU represents the first level of

the inspection system and has a direct authority over the establishments that are certified for export to the U.S. The in-plant inspection represents the second level of inspection level and is headed by the Veterinary Officer (VO).

Official verification and inspection activities are conducted at all certified establishments in accordance with uniform instructions disseminated from the CCA to the field via email, telephone, and hard copy. Updates and additional instructions to personnel concerning established regulations, programs, and manuals are published and disseminated as guidelines. These programs and manuals contain procedures to assist official personnel to uniformly assess the adequacy of food safety measures implemented by establishments certified to export meat products from Finland to the U.S. and enforce the regulations of the Finnish inspection system. The FSIS auditor performed on-site observations and reviewed records maintained by inspection personnel at headquarters and in-plant EVIRA inspection offices. These records are detailed in the following equivalence components. The FSIS auditor determined that regulatory verification and inspection activities were consistently implemented at all establishments audited. Officials use the authority conferred upon them by the laws of Finland to enforce the rules of the meat inspection system, identify and document non-compliances, and verify the adequacy of corrective actions and preventive measures.

The enforcement strategies in place are based on EU regulation 882/2004, Finnish *Food Act* and EVIRA's guideline 19002/4. The Finnish *Food Act*, Chapter 10, explains penalties for health offences violating the provision of this Act. The CCA has controls in place to prevent fraud or misuse of export health certificates. This is accomplished by issuing export health certificates on secure watermarked paper.

The FSIS auditor verified that the CCA provides ongoing training program that intended to ensure that inspection officials are aware of specific inspection requirements that pertain to Finland's meat export to the United States. In addition, in November 2009, 2010 and 2011, the CCA organized a one-day training course regarding general FSIS import requirements for establishment's personnel in eligible establishments.

Since the last FSIS audit, the CCA organized several two-day training courses for the veterinary officers in the U.S. eligible establishments as follow:

- November 2009: enforcement actions, visual inspection and FVO audit results.
- March 2010: animal welfare, infectious diseases and animal transport requirements.
- October 2010: animal diseases, work welfare and establishment's approval process.
- February 2011: information security, animal welfare and export.
- October 2011: animal welfare, animal identification and general meat inspection.
- February 2012: visual inspection and meat inspection law.

The CCA also organized several two-day training courses for non-veterinary inspectors in the U.S. eligible establishments as follow:

- October and November 2009: meat inspection, animal diseases and zoonotic diseases.
- February and March 2010: meat inspection, animal diseases and by-products.

- November 2010: meat inspection, animal diseases and by-products.
- March and May 2011: information security, work welfare and export requirements.
- November 2011: sanitation procedures, by-products and ante-mortem inspection.
- March/April 2012: zoonotic diseases, work health and results of general FVO audit.

The FSIS auditor reviewed the inspection personnel's training records at the headquarters and local inspection offices. This review indicated that in-plant inspection personnel have completed their required classroom training.

The CCA is responsible for hiring and assigning qualified inspection personnel, based on *Statutes no. 38/EE/2006*, to perform inspection and enforcement activities at the certified establishments. The FSIS auditor reviewed documentation to ascertain that Veterinary Medical Doctors had the required veterinary degree and that inspectors had the required pre-employment training program and education. This documentation was reviewed for a sampling of individuals including both veterinarians and inspectors at the headquarters and in-plant levels. All training records reviewed showed that veterinary personnel had degrees in veterinary medicine and that inspectors had certificates attesting to their required pre-employment training programs. In Finland, veterinarians take meat inspection courses in the curriculum of their formal education. Non-veterinary inspectors ("auxiliaries"), in accordance with EC regulation 854/2004, have inspection courses involving 400 hours of practical training on the slaughter line and 500 hours of theoretical class work, after which they must pass specific examinations before being qualified to work in export meat establishments. The CCA in cooperation with Finnish Meat Research Institute (FMRI) provides these training courses.

The FSIS auditor reviewed *Food Act 23/2006*, Chapter 8, and pay stubs to verify that the CCA operations are funded by the government budget, in accordance with the *Act*. The inspection personnel assigned at the establishments certified to export meat products to the U.S. are employees of the national government who are identified by ID cards.

The FSIS' review of the inspection activities carried out at both levels of the inspection system indicated that the EC regulations are the primary overarching laws for regulating meat inspection, enforcing inspection laws and ensuring that adulterated or misbranded products are not exported to the United States. In addition, Finland has issued national legislations to address the implementation of the inspection activities. The national legislation related to meat inspection includes; *the Food Act (23/2006)* and *the Meat Inspection Act (1470/2011).* The head of MIU issues guidelines and instructions that deal with the frequency of supervisory review; 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 Directive 96/22 and 96/23. The CCA disseminates inspection information related to the regulatory and administrative affairs electronically to establishments certified to export product to the US.

Initial and annual ongoing certification of establishments for export to the U.S. is performed by the headquarters of the CCA. The CCA has a written protocol based on *Food Act*, Section 14, "*Application Procedure for Approval of Food Premises*" that describes the procedures that

establishment operators should 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 conducts the initial export approval determinations through a comprehensive establishment's audit which consisted of establishment's document review including HACCP, sanitation, and sampling document as well as one or more on-site visit of the establishment to verify that all regulatory requirements specific to an importing country has been met. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing US-certified establishment to maintain its eligibility to export to the United States. The FSIS auditor reviewed electronic and hard copy of registration form, initial approval determinations, and certification documents maintained by government officials at the CCA headquarters. These documents include sections that correspond to the sanitation requirements, for facility maintenance, SSOP and HACCP programs, and generic *E. coli* testing. FSIS verified that the CCA officials have conducted the approval process in accordance with Finland's prescribed procedures.

The *Food Act*, Section 61, outlines the procedures for *"Cancelling the Approval of Food Premises"* by the CCA. EVIRA may issue a warning letter of cancellation on the basis of observations made by inspection personnel for HACCP, SSOP, or other non-compliances. The warning letter is similar to FSIS's NOID letter with the same 30 days time frame for correcting the non-compliance. 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's guideline 19002/4 describes the official veterinarians' responsibilities regarding the official process for suspension, delistment, and re-listment of certified establishments.

The CCA demonstrated they are capable of tracking export certificates issued for a specific country. This tracking system relied on the issuance of unique identification number for each certificate and the maintenance of records that included signature card for each authorize veterinarian. In addition, export seals, stamps, and health certificates were secured at the official inspection office.

The laboratory system consists of two government and two private laboratories that conduct analytical testing of product destined for the United States. The Chemistry and Toxicology Laboratory, a government laboratory, is responsible for conducting national residue analyses. The Kuopio Research Unit, another government laboratory, is responsible for confirming and serotyping of the positive *Salmonella* results. The two private laboratories are responsible for *Salmonella* and *E. coli* analytical testing. The CCA approves the eligibility of private laboratories for conducting microbiological testing in accordance to *Food Act* requirements.

The FSIS auditor visited the Chemistry and Toxicology Laboratory which has been identified as the National Reference Laboratory for all commodities and all substance groups listed in Annex 1 of Council Directive 96/23/EC. This laboratory is accredited according to ISO 17025 and is reviewed by Finnish Accreditation Service (FINAS) annually. FINAS is identified by the Finnish law 921/2005 as the national accreditation body responsible for organizing the accreditation activities according to the international criteria. FINAS offers accreditation service to government and private laboratories and audit these laboratories annually. The CCA, as part of its oversight responsibilities, conducts annual reviews and audit of the laboratories which are responsible for testing of product destined for export to the U.S. The CCA annual audit report

includes administrative and technical aspects of the analytical methodology, laboratory personnel qualifications and training, and maintenance of the laboratory equipment. The FSIS auditor reviewed the CCA and FINAS audit reports and its related follow up reviews. No concerns arose as the result of these reviews.

In conclusion, there were no system findings in Finland's adherence to the criteria for organizational structure and staffing, ultimate control and supervision, the assignment of competent qualified inspectors, the authority and responsibility to enforce the laws and adequate administrative and technical support including laboratory oversight and the application of procedures and standards that are equivalent to the U.S. requirements. Therefore, this component of the system continues to meet equivalence criteria.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The auditor verified that the inspection system was organized and administered by the national government of Finland. The auditor also verified that the system provided 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

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. The FSIS auditor verified that official inspection and verification activities followed responses from the SRT and supporting documentation.

The FSIS auditor accompanied and observed the application of the off-line veterinarian verification activities for ante-mortem/humane handling and slaughter, post-mortem examination, *Salmonella* and generic *E. coli* sample collection, verification of pre-operational and operational sanitary procedures, HACCP verification activities including the zero tolerance CCP verification and performance evaluation of on-line inspectors. No concerns arose as the result of these observations.

The FSIS auditor notified that Finland, as European Union Member State, participates in the European Commission (EC) *Salmonella* eradication program. The program requires *Salmonella*-free flock certification for all flocks intended to be presented for slaughter.

During the on-site audit of slaughter establishments, the FSIS auditor observed the function of inspection personnel while performing ante- mortem inspection activities at the holding pens.

The inspection personnel conducted ante-mortem inspection on the day of slaughter by reviewing the in-coming registration and identification document with each load/truck and observing all swine at rest and in motion from both side in designated holding pens in order to determine whether they are fit for slaughter. There was a separate pen marked for examination of suspect animals. The FSIS auditor observed and verified that all animals had access to water at all times in all holding pens, including the suspect pen, and if held overnight then feed would be provided. The auditor concluded that the implementation of the ante-mortem inspection was in compliance with EU and Finnish regulations. This also met applicable portions of FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection".

The FSIS auditor also observed in-plant inspection verification of humane handling procedures including the use of carbon dioxide gas (CO2) chamber, gas concentration and its exposure time in order to render all animals insensible to pain before being shackled or cut. Gas-producing and control equipment were maintained in good repair and available for inspection.

FSIS assessed technical aspects of post-mortem inspection at three U.S. certified swine slaughter establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. Both in-plant veterinary and non-veterinary inspectors were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the swine heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes were made in accordance with EU regulations which have been recognized as equivalent to FSIS requirements. This also met applicable portions of FSIS Directive 6100.2 "Post-Mortem Livestock Inspection". The design of the post-mortem inspection stations including proper lighting and the number of on-line inspectors also met Finland's requirements.

The presence of a veterinary inspector during post-mortem examination was regulated in chapter II of appendix I of the *Food Act*. The veterinary inspector was responsible for supervising on-line non-veterinary inspectors and post-mortem inspection activities including disposition of suspect carcasses and parts.

The FSIS auditor also observed the functions of the off-line veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities. These daily verification activities included direct observation, direct measurement and review of establishment's records, including HACCP, sanitation, and sampling records, in accordance with the CCA weekly inspection task plans outlined in Finnish document titled "*n vientiin hyvaksyttyjen laitosten viranomaisvalvonta*". The inspection personnel performance was routinely evaluated and documented by the CCA supervisors in periodic supervisory reviews. No concern arose as a result of FSIS observations.

The auditor also reviewed and verified the application of periodic supervisory reviews at the CCA headquarter and local inspection offices. The SO of the MIU conducts periodic supervisory reviews in accordance with updated EVIRA's guidelines "*Requirements for Export to the USA*" 19002/4 (2012) for inspection personnel and 19001/4 (2012) for establishment operator. These

guidelines contain inspection's instructions, procedures regarding implementation, documentation, and corrective actions for:

- HACCP procedures in accordance with 9 CFR part 417 and EVIRA's HACCP guideline No. 10002/2. The frequency of HACCP procedures verification by inspection personnel is set at the minimum of twice per week.

- Sanitation procedures in accordance with 9 CFR part 416 and Finnish sanitation guideline No. 662/32/03. The frequency of sanitation procedures verification by inspection personnel is set as daily.

- *Salmonella* sampling in accordance with 9 CFR part 310.25 and Finnish national *Salmonella* regulation No. 20/EEO/2001. The frequency of *Salmonella* sampling is set by the CCA and it contains both carcasses and lymph nodes sampling and testing, 4) *E. coli* sampling in accordance with 9 CFR part 310.25 for generic *E. coli* and EU regulation 2001/471/EC for *Enterobacteriaceae*. The frequency of *E. coli* and *Enterobacteriaceae* sampling is based on aforementioned regulations in this paragraph.

Currently, the CCA conducts ten (for slaughter/cutting establishments) and six (for cold storage facilities) periodic supervisory reviews per year. FSIS did not audit any cold storage facilities during this audit. The supervisory reviews were conducted using a uniform detailed checklist. The periodic supervisory reviews evaluate the adequacy of establishment food safety system and the capability of inspection personnel for conducting inspection activities at certified establishments. During the periodic supervisory reviews, the CCA supervisors observe and determine the knowledge, skills, and abilities of inspection personnel for conducting assigned responsibilities.

The FSIS auditor reviewed the HACCP, SSOP, and sampling verification records as well as non-compliance reports (*Epakohtaraportti*) that were generated by the in-plant inspection personnel at three audited establishments. FSIS noted that the inspection personnel have identified and documented deficiencies in a non-compliance record (NR). The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventative measures. The FSIS auditor reviewed all open and closed NRs issued from January 1, 2012 to the day of the audit (less than 10 NRs in total for SSOP, HACCP, and SPS non-compliances) and verified that the inspection personnel have followed the established procedures cited in EVIRA's guideline 19002/4. The FSIS auditor also reviewed several supervisory reviews to assess the enforcement capability of the inspection personnel and the adequacy of establishment's corrective actions. No concerns arose as the result of these observations. The FSIS auditor also verified that all the non-compliances reported during the last FSIS audit were adequately addressed and corrected. The conditions in the plant matched the supervisory reviews, and there was no indication that there were any non compliance trends with SSOP, HACCP, SPS or activities related to slaughter.

In conclusion, Finland's meat inspection system has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of meat inspection organized

and maintained by the United States. Therefore, this component of the system continues to meet equivalence criteria.

7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, interview of government officials, and observations made by the FSIS auditor during the on-site audit of government offices and three certified slaughter establishments.

The CCA demonstrated that it enforces overarching EU sanitary regulations which have been determined to be equivalent to FSIS requirements. In addition, Finland incorporated FSIS regulation 9 CFR part 416 into its export requirements for the United States. Finnish sanitation guideline No. 662/32/03, EVIRA guideline No. 19001/4 for the establishment personnel and EVIRA guideline No. 19002/4 for official veterinarians of the U.S. eligible establishments provide instructions in order to meet FSIS sanitation requirements. The in-plant inspection personnel at certified establishments conducted verification of sanitary conditions in accordance with EVIRA's guideline 19002/4 which included 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 FSIS auditor observed the in-plant inspector conducting pre-operational sanitation verification of slaughter and processing/cutting rooms in one of the audited establishments. The in-plant inspection's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined the facility was ready for in-plant inspector pre-operational sanitation verification activities. During the hands-on verification, the in-plant inspector conducting pre-operational inspection found small meat product particles in two different cutting tables in the processing room. The establishment management took corrective action by removing meat particles, re-washed and re-sanitized the affected food contact surface. The inspection verified the implementation of the corrective action before the start of the operation. These actions recorded in both establishment and inspection verification records. The in-plant inspector verification activities also included a pre-operational record review including the results of the previous day's establishment microbiological testing results, in accordance with EU regulation 2073/2005, 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, structural integrity) by official inspectors.

At one audited establishment, the FSIS auditor noted rust, approximately one inch in size, on the lower part of a leg of a table on the cutting room. This was not a food contact surface and the establishment personnel removed this table from the production area for immediate repair. This finding did not have a significant impact on the overall sanitary condition of the establishment or performance of Finnish inspection system.

The FSIS auditor followed the off-line veterinary inspector and observed in-plant inspection verification of operational sanitation procedures at audited establishments. These verification activities included direct observation of operational process and review of establishment's operational records in accordance with the CCA weekly and monthly assigned inspection tasks plan. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection's verification records for the same time period. FSIS auditor noted that the inspection and establishment records were mirroring the actual sanitary condition of the establishment. The audited establishments did maintain sanitation records sufficient to document the implementation and monitoring the SSOP and any corrective actions taken. The establishment employee(s) specified as being responsible for the implementation and monitoring of the SSOP procedures authenticated these records with initials or signatures and the date. No concern arose as the result of this review.

During the audit of three slaughter/cutting establishments, the FSIS auditor reviewed non-compliance records generated by in-plant inspection personnel since January 2012. The auditor noted that establishment's management have completed all sections of each NR properly addressing corrective action requirements including procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product. The NRs were closed by inspection officials after verifying the adequacy and effectiveness of the establishment's corrective actions.

The FSIS auditor made a comparison between actual sanitary conditions of the audited establishments for both pre-operational and operational sanitation. The FSIS auditor also reviewed in-plant inspection's documented non-compliances, inspection's verification of corrective actions and establishment's corrective action records, and the results of the periodic supervisory reviews in regard to overall sanitary condition of the establishments.
These comparison and reviews were in direct correlation with FSIS observations and there were no significant findings to report after consideration of the nature, degree and extent of all observations.

As a result of this comparison, FSIS determined that the inspection system provided requirements equivalent to those of FSIS system for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. In-plant veterinary officials and the CCA senior officer were well trained and enforced these regulatory requirements while monitoring the ability of the establishments to maintain sanitary conditions.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement and maintain a HACCP plan. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and on-site observations made by the FSIS auditor during the audit of government offices and three certified establishments. Finland met the criteria for this component.

The FSIS auditor reviewed EVIRA guidelines No. 19002/4 and No. 10002/2 and compared the contents of the audited establishment's HACCP plans with corresponding establishment's monitoring, corrective actions, and verification records as well as Finnish inspection's verification records for the past six months. The FSIS auditor's review indicated that the HACCP documents generated by establishment and inspection personnel were in compliance with EVIRA's HACCP guideline No. 10002/2 and adopted FSIS requirements cited in 9 CFR part 417.

At one of the audited establishments, HACCP verification records (record review component) for CCP 1 (zero tolerance CCP) did not include the time for several entries. The verification records for direct observation and calibration of instruments included the time for all the entries. This finding did not have a significant impact on the overall condition of the establishment or the oversight verification function of Finnish inspection system.

FSIS also observed that the in-plant inspection personnel, at certified establishments, conducted daily verification of HACCP plans in accordance with aforementioned Finnish guideline No. 10002/2. The inspection's verification activities included the review of the establishment's written HACCP plans and its contents, review of HACCP records generated by establishment's responsible personnel, hands-on inspection verification of establishment's CCPs monitoring and verification activities, and inspection verification of implementation of establishment's corrective actions when there is a deviation from the critical limits.

The FSIS auditor reviewed establishment's records for zero tolerance CCP generated within the last six months. In addition, FSIS auditor reviewed the in plant inspection's s zero tolerance CCP verification records for visible ingesta, feces and milk on swine carcasses. Establishments recorded a few deviations from the critical limits while inspection verification record showed no deviation at zero tolerance CCP for the same time frame. No trends were detected as the result of these document reviews. During a period of 10 to 15 minutes, FSIS auditor stood at zero tolerance CCP location and not only observed the inspection personnel conducting HACCP hands-on verification activities at this CCP but also made a direct examination of swine carcasses. This CCP location met Finnish requirement including the illumination of at least 540 lux for proper examination. No deviation from the critical limits was observed by the inspection personnel or FSIS auditor at the day of the audit.

The review of the establishment's corrective actions in response to deviation from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance to 9 CFR part 417, were addressed by audited establishments and verified by the inspection personnel. The corrective action included:
1) identifying and eliminating the cause of the deviation from a critical limit. The causes was determined be an equipment malfunction or employee's error;
2) Bringing the CCP under control after the corrective action is taken. This may achieve by increasing the monitoring frequency by establishment personnel. The inspection may increase its verification frequency to ensure that the establishment proposed corrective actions are sufficient;
3) applying measures to prevent recurrence such as equipment adjustment and employee's training; and

4) assurance no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce. This included an examination of all affected swine carcasses back to the last acceptable check by the establishment.

The FSIS auditor review of documents pertaining to hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments as well as on-site observation of the inspection personnel in action indicated an adequate HACCP food safety system in the audited establishments.

In conclusion, the results of the assessment of the HACCP programs and inspection oversight demonstrated that Finland's inspection system continues to provide requirements equivalent to those of FSIS.

9. CHEMICAL RESIDUES CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth of the six equivalence components. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. In addition, the CCA must provide a description of the actions taken to deal with unsafe residues as they occur as well as measures to deter recurrence. The CCA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data. Finland's system met the criteria for this component.

Finland's national residue program and its implementation and results were reviewed by the FSIS's headquarter experts prior to the audit. This was an in-depth review and analysis of Finland's residue program documentation submitted to FSIS as support for the responses provided in the SRT (2009 version). In addition, a review of the FSIS's Automated Import Inspection System (AIIS) database indicated that there have not been any chemical residue related POE violations since the last FSIS audit.

During the on-site audit, FSIS reviewed Finland's Chemical Residue Control Programs at the CCA's headquarters, three audited slaughter establishments, and the national reference residue laboratory to verify the implementation and enforcement of the regulatory requirements. The FSIS auditor interviewed the CCA officials and the in-plant inspectors to verify the proper implementation of the National Residue Program at both inspection levels. The National Residue Reference Laboratory was audited in which the FSIS auditor observed and verified sample handling, sampling frequency, trace back of a selected sample by auditor from a US eligible establishment to verify timely analysis and data reporting to the CCA, application of approved analytical methodologies and use of proper tissue matrices, equipment operation and printouts, acceptable detection levels and percent recoveries, intra-laboratories check samples, and laboratory quality assurance programs including standards books and corrective actions. No concerns arose as a result of these observations and reviews.

The FSIS auditor verified that Finland's residue control program is designed and conducted in accordance with *Council Directive 96/23/EC of 29 April 1996*. The CCA official control

measures and enforcement actions are defined in Chapter IV which includes the CCA responsibilities to obtain information when positive or violative results occur, to identify the animal and farm of origin, to investigate the cause of the violation at the farm, to safeguard the public health by product disposition, to intensify the checks on the animals and products from the farm, and to impose criminal or administrative penalties against any person who is responsible. This directive has been recognized as equivalent by FSIS. The FSIS auditor concluded that the program was effectively implemented at all levels and Finland's national residue testing program for 2012 was being followed and was on schedule.

In conclusion, Finland's meat inspection system has a residue control program that continues to meet equivalence requirements.

10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and administered by the national government. The evaluation of this component included a review and analysis of documentation (EC regulation 2073/2005) previously submitted by the CCA as support for the responses provided in the SRT (2009 version) and on-site observations made by the FSIS auditor at government offices, establishments, and a microbiology laboratory. A review of the Ready to Eat (RTE) program was not included in the scope of the audit since Finland does not have equivalence determination to export RTE products to the U.S.

The microbiological sampling and testing program is intended to ensure that meat products produced for export to the U.S. are safe, wholesome and unadulterated. The criteria the FSIS used to assess microbiological testing programs included:

- The inspection system provides for a sampling and testing program for generic *E. coli* or *Enterobacteriaceae* in raw meat product, and the CCA uses the test results to verify establishment slaughter processing and dressing controls for fecal contamination. *E. coli* sampling is in accordance with adopted 9 CFR part 310.25 for generic *E. coli* and EU regulation 2073/2005for *Enterobacteriaceae*. FSIS reviewed the generic *E. coli* written procedures and verified that establishments were sponging swine carcasses to evaluate generic *E. coli* test results by using statistical process control techniques showing at least the most recent 13 test results. FSIS also observed the sample collection procedures at audited establishments to verify aseptic technique, and sampling procedures. A review of the sampling results for the last 90 days indicated that the establishments routinely met their limits as determined by statistical process control. FSIS did not note any non-compliance while reviewing the establishment's generic *E. coli* testing program.

- The inspection system provides for a sampling and testing program for *Salmonella* in raw product, and includes performance standards for *Salmonella*. The inspection system achieves pathogen reduction by ensuring that all slaughter establishments meet the *Salmonella* Performance Standards. *Salmonella* sampling is in accordance with 9 CFR part 310.25 and Finnish national *Salmonella* regulation No. 20/EEO/2001. The frequency of *Salmonella*

sampling is set by the CCA and it contains both carcass and lymph nodes sampling and testing. FSIS applied the same verification methodology as it was stated for generic *E. coli* and concluded that *Salmonella* sampling was in compliance with aforementioned regulatory requirements.

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. At the in-plant level, the FSIS auditor observed and verified microbiology sample collection, handling, and shipping of official samples to accredited government or private laboratories. This process was under the oversight of the CCA and in accordance with its sample collection protocols described in EVIRA's guideline 19002/4 and Finnish national *Salmonella* regulation No. 20/EEO/2001.

During the laboratory visit, verification focused on the qualification of analysts, sample receiving and handling, analytical methodology, data reporting, maintenance of facilities and equipment, and corrective actions. FSIS reviewed the CCA's auditing procedures, checklists and results of past audits and verified that the CCA and FINAS on routine basis evaluate the functions of this laboratory. No concerns arose as a result of this visit.

11. EXIT MEETING

An exit meeting was held on June 20, 2012, in Helsinki with the CCA representatives. At this meeting, the preliminary observations from the audit were presented by the FSIS auditor.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

FSIS concluded that the CCA was able to meet the U.S. import requirements for the equivalence components (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs. The current audit did not identify any systemic findings within the six equivalence components.

Nader Memarian, DVM
Senior Program Auditor

13. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Finland Response to Draft Final Audit Report

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
HK Ruokatalo Oy Teollisuuskatu 17 Forssa 30420	06/15/2012	18	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[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 SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

45/51 Rust, approximately one inch in size, was observed on the lower part of a leg of a table on the cutting room [9CFR 416.2(b)]. This was not a food contact surface. The establishment removed the table from the production area for immediate repair.

A review of the enforcement records, from January 2012 to the day of the audit, indicated that the Finnish inspection service had issued three non-compliance records (NR) documenting SPS related findings. None of the NRs were associated with this finding.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	

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 Oyj PL 900 Nurmo 60550	06/12/2012	22	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

22/51 The establishment's HACCP verification records (record review component) for CCP 1 (zero tolerance CCP for fecal, ingesta, and milk) did not include the time for several entries. The verification records for direct observation and calibration of instruments included the time for all the entries [9 CFR § 417.5, and 417.8]. The establishment decided to modify the record adding a box for entering verification time.

A review of the enforcement records, from January 2012 to the day of the audit, indicated that the Finnish inspection service had issued two non-compliance records (NR) documenting HACCP related findings. None of the NRs were associated with this finding.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	

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
HK Ruokatalo Oy Ysitie 387A Mellila 32300	06/14/2012	85	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[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 SSOPs 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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	

Evira

Meat Inspection Unit

Pvm/Datum/Date
17.5.2013

Dnro/Dnr/DNo
3245/0929/2012

Dr Shaukat H.Syed
Director, International Audit Staff
Office of International Affairs
Food Safety and Inspection Service

1400 Independence
20250 WASHINGTON, D.C.

THE DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN FINLAND JUNE 5 TROUGH JUNE 20, 2012

To whom it may concern,

Please find enclosed the comments of the Finnish Food Safety Authority on the draft audit report 2012. We only have a small comment to one point. Please kindly check that the page numbering in contents corresponds to the text.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS
Second paragraph, page 16, first sentence should read: At one of the audited establishments, HACCP verification records (record review component) for CCP 1 *(0-tolerance for faecal carcass contamination)* did not include the time for several entries.

The same comment to another place in the report:

13. ATTACHMENTS TO THE AUDIT REPORT
13.1 Foreign Establishment Audit Checklist 06/12/2012
Point 60, Observation of the Establishment, first sentence should read: The establishment's HACCP verification records (record review component) for CCP 1 (*0-tolerance for faecal carcass contamination*) did not include the time for several entries.

Please find attached the reports of the Finnish auditor's on the 6/12/2012 audit.

Yours sincerely,

Head of Unit
Meat Inspection Unit

Eeva-Riitta Wirta

Senior Officer
Meat Inspection Unit

Tuomas Haltiala

Evira

LIHANTARKASTUS- JA VALVONTAYKSIKKÖ
Mustialankatu 3, 00790 HELSINKI
Puhelin 029530 0400 Telekopio 029530 4350

Päiväys 23.7.2012 **Dnro** 691/0921/2012

USA:n vientiin hyväksytyn laitoksen valvojan auditointi

Laitoksen nimi:	Atria Oy, Nurmo
Laitoksen hyväksymisnumero:	22
Valvontaviranomainen:	Valtion tarkastuseläinlääkäri
Auditointipäivämäärä:	12.06.2012
Auditoinnin suorittaja:	Ylitarkastaja Sirpa Kemilä, Evira

Auditoinnissa läsnä:

valvontaviranomaiset:	Ylitarkastaja Tuomas Haltiala, Evira Johtava tarkastuseläinlääkäri Irmeli Sippola, Evira Tarkastuseläinlääkäri Marja Fossi, Evira
USDA/FSIS:in edustajat:	Dr. Nader Memarian, USDA, FSIS
laitoksen edustajat:	Lihalinjan johtaja Markku Hirvijärvi Tuotantopäällikkö Pekka Honkaranta Leikkaamon esimies Rainer Roukala Teurastamon esimies Jari Kujanpää Hygieniapäällikkö Vesa Mäntynen Omavalvoja Tiina Kinnunen ISS:n päällikkö: Minna Vornanen ISS:n työnjohtaja: Janne Keskitalo

Allekirjoitus:

Yleistä

Kyseessä oli USA:n maatalousministeriön (USDA) tarkastuksen yhteydessä suoritettu auditointi. Tarkastuksen teki Dr. Nader Memarian. Alkukokouksessa tarkastaja kertoi, että hän kiinnittää erityisesti huomiota laitosten HACCP- ja SSOP-vaatimuksiin, E.*coli* sekä Salmonella valvontaohjelmiin, Elintarviketurvallisuusviraston (Evira) ja tarkastuseläinlääkäreiden suorittamaan laitosten valvontaan.

Loppukokouksessa tarkastaja totesi että järjestelmällisiä puutteita laitoksista tai Suomen valvontajärjestelmästä ei löytynyt.

Auditoinnin aiheet

Auditointisuunnitelman aiheet

1 Elintarviketurvallisuusviraston auditointisuunnitelman aiheet kuukaudelle olivat:

1. sivutuoteohjelma,
2. SPS/SOP-ohjeiden toteuttamisen valvonta tuotannon aikana leikkaamossa,
3. SSOP-ohjelman toteuttamisen valvonta tuotannon aikana leikkaamossa,
4. sivutuotteiden käsittely ja
5. tarkastuseläinlääkäreiden valvontasuunnitelma ja -kirjanpito pyydettävin osin.

Auditointisuunnitelman seuranta-aiheet

2 Eviran auditointisuunnitelmassa ei ollut seuranta-aiheena.

Auditointisuunnitelman lisäaiheet

3 USDA:n tarkastajalla oli lisätoivomuksena auditointisuunnitelman aiheisiin seuraavat lisäaiheet:

1. teurastamon HACCP-ohjelma,
2. teurastamon HACCP-ohjelman toteuttamisesta laadittu kirjanpito,
3. leikkaamon HACCP-ohjelma,
4. leikkaamon HACCP-ohjelman toteuttamisesta laadittu kirjanpito,
5. lähtötarkastuksen ohjelma,
6. lähtötarkastuksen toteuttamisesta laadittu kirjanpito,
7. teurastamon SSOP/SOP-ohjelma ennen tuotannon aloittamista,
8. teurastamon tuotannon aikainen SSOP/SOP-ohjelma,
9. teurastamon SSOP/SOP-ohjelman ennen tuotannon aloittamisen toteuttamisesta laadittu kirjanpito,
10. teurastamon SSOP/SOP-ohjelman tuotannon aikaisesta toteuttamisesta laadittu kirjanpito,
11. leikkaamon SSOP/SOP-ohjelma ennen tuotannon aloittamista,
12. leikkaamon tuotannon aikainen SSOP/SOP-ohjelma,
13. leikkaamon SSOP-ohjelman ennen tuotannon aloittamisen toteuttamisesta laadittu kirjanpito,
14. leikkaamon SSOP-ohjelman tuotannon aikaisesta toteuttamisesta laadittu kirjanpito,
15. salmonellavalvontaohjelma,
16. tarkastuseläinlääkäreiden valvontasuunnitelmat ja –kirjanpito,
17. tarkastuseläinlääkäreiden laitokselle kirjoittamat epäkohtaraportit,
18. ante mortem-kirjanpito,

Tarkastuskierros:

19. ennen tuotannon aloittamista tehtävä aistinvarainen puhtauden tarkastaminen leikkaamossa,
20. ennen tuotannon aloittamista tehtävä aistinvarainen puhtauden tarkastaminen teurastamossa,
21. leikkaamon tuotannon aikaisen toiminnan tarkastaminen,
22. ruhovaraston siisteys ja rakenteiden kunto,
23. *E-coli* näytteenoton asianmukaisuus,
24. SPS/SOP-ohjeiden toteuttamisen valvonta työntekijöiden sosiaalitiloissa,
25. teurastamon tuotannon aikaisen toiminnan tarkastaminen,
26. lihantarkastajien suorittaman post mortem-tarkastuksen asianmukaisuus,
27. sivuraiteen toiminta ja
28. eläinten käsittely ja tainnutus navetassa.

Valvontasuunnitelman aiheet

4 Tarkastuseläinlääkäreiden valvontasuunnitelman aiheet päivälle olivat samat kuin auditointisuunnitelman aiheet.

Valvontasuunnitelman seuranta-aiheet

5 Tarkastuseläinlääkäreiden valvontasuunnitelman oli seuranta-aiheena:

1. kaikki vuoden 2009 USDA:n auditoinnilla havaitut epäkohdat.

Valvontasuunnitelman lisäaiheet

6 Tarkastuseläinlääkäreiden valvontasuunnitelmassa ei ollut lisäaiheita.

Auditoinnin yhteydessä tehdyt havainnot

Tarkastuseläinlääkäreiden valvontasuunnitelma

7 Tarkastaja tarkasti tarkastuseläinlääkäreiden viikkovalvontasuunnitelmia.

Tarkastuseläinlääkäreiden valvontakirjanpito

8 Tarkastaja tarkasti tarkastuseläinlääkäreiden viikkovalvontakirjanpidosta muutamia viikkovalvontakirjanpitoja.

9 Tarkastaja tarkasti navetassa ante mortem-kirjanpitoa.

10 Tarkastaja tarkasti tarkastuseläinlääkäreiden kirjoittamia epäkohtaraportteja.

Tarkastuseläinlääkäreiden toiminta; laitoksen omavalvonta-ohjelmien, toiminnan ja kirjanpidon tarkastaminen

11 Tarkastaja tarkasti SPS/SOP-ohjeiden ja SSOP-ohjelman toteuttamisen valvontaa tuotannon aikana leikkaamossa. Tarkastaja tarkasti ensimmäisenä vastaanottotarkastuksen toiminnan. Hän havaitsi vastaanottotarkastuksen jälkeen yhden ruhon, jossa oli suolen sisältöä pään alueella. Laitoksen edustajat tekivät välittömästi korjaavat toimenpiteet ja tarkastuseläinlääkäri kirjoittaa epäkohdasta epäkohtaraportin. Puhdistuspöydällä havaittiin lisäksi kaksi ruhoa päällekkäin ja laitoksen edustajat ryhtyivät korjaaviin toimenpiteisiin välittömäs-

ti. Seuraavaksi mentiin uuden leikkaamon puolella, jossa havaittiin leikkaamon puhtaissa valkoisissa lihalaatikoissa pieniä mustia pisteitä jotka olivat peräisin laatikkokuljettimesta. Laitoksen edustajat lopettivat leikkaamon toiminnan tässä osassa, jossa ongelma esiintyi ja ryhtyivät muihin tarvittaviin korjaaviin toimenpiteisiin. Tarkastaja tarkasti myös leikkaamon rakenteita ja yksi viimeistelemätön ilmastointihormi havaittiin leikkaamon puhdistusalueella. Lopuksi tarkastettiin vielä lajitelmavarasto, lavaamo ja muutama leikkuulinja. Laitoksen edustajat tekivät kaikki tarvittavat korjaavat toimenpiteet välittömästi ja tarkastuseläinlääkäri ei havainnut huomauttamista heidän toiminnassaan. Tarkastuseläinlääkärit seuraavat viikkovalvonnassa tarkastuksessa havaittuja epäkohtia useammin ja, että seurantaan jääneet kohteet korjataan mahdollisimman nopeasti.

Tarkastuseläinlääkäreiden toiminta; auditointisuunnitelman lisäaiheiden tarkastaminen

12 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon HACCP-ohjelman. Laitoksen edustaja esitteli ohjelmasta vuokaavion, vaara-analyysin ja suunnitelman. Tarkastaja oli sitä mieltä, että vaara-analyysissä tulisi olla paremmin perusteltu, miksei jossain kohdassa ole vaaraa. Hänen mielestään perustelut voivat olla joko vaara-analyysissä tai sitten jossain muissa papereissa. Tarkastajan mielestä ohjelmassa mainitut korjaavat toimenpiteet, jotka tehdään kun kriittisessä hallintapisteessä on havaittu poikkeama eivät olleet aivan riittävät. Hän huomautti, että korjaavien toimenpiteiden tulee käsittää myös paremmin toimenpiteet, joilla varmistetaan, että kriittinen hallintapiste on saatu hallintaan. Tämä voidaan hänen mielestään tehdä lisäämällä seurantatarkastuksia kriittisessä hallintapisteessä ja näin voidaan varmistaa, että korjaavat toimenpiteet kuten esim. automaattien tarkastukset, ovat olleet riittävät ja kriittinen hallintapiste on saatu hallintaan. Tarkastajalla ei ollut muuta huomauttamista vuokaavioon, vaara-analyysiin tai suunnitelmaan. Tarkastuseläinlääkärit seuraavat viikkovalvonnassaan, että tarkastuksella havaitut epäkohdat korjataan.

13 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon HACCP-ohjelman toteuttamisesta laadittua kirjanpitoa. Laitoksen edustaja esitteli monitorointikirjanpitoa. Tarkastaja huomautti, että seurantalomakkeesta puuttui kohta ylimääräisille seurannoille. Seuraavaksi laitoksen edustaja esitteli todentamiskirjanpitoa. *Tarkastaja huomautti, että kaikkiin kirjauksiin tulee merkitä päivämäärä, kellonaika ja tarkastuksen tulos. Samoin hän sanoi, että ruhovarastossa tehtävien ruhojen uudelleen tarkastuslomakkeeseen tulee myös merkitä kellonaika, jolloin uudelleen tarkastus on aloitettu ja lopetettu.* Tarkastajalla ei ollut muuta huomauttamista kirjanpitoon. Tarkastuseläinlääkärit seuraavat viikkovalvonnassaan, että tarkastuksella havaitut epäkohdat korjataan.

14 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon HACCP-ohjelman. Laitoksen edustaja esitteli ohjelmasta vuokaavion, vaara-analyysin ja suunnitelman. Tarkastajalla ei ollut huomauttamista ohjelmaan.

15 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon HACCP-ohjelman toteuttamisesta laadittua kirjanpitoa. Tarkastajalla ei ollut huomauttamista kirjanpitoon.

16 Tarkastaja pyysi laitoksen edustajaa esittelemään lähtötarkastuksen ohjelman. Laitoksen edustaja esitteli ohjelman. Tarkastajalla ei ollut huomauttamista ohjelmaan.

17 Tarkastaja pyysi laitoksen edustajaa esittelemään lähtötarkastuksen toteuttamisesta laadittua kirjanpitoa. Laitoksen edustaja esitteli kirjanpitoa. Tarkastajalla ei ollut huomauttamista kirjanpitoon.

18 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon ennen tuotannon aloittamista laaditun SSOP/SOP-ohjelman. Laitoksen edustaja esitteli ohjelman. Tarkastajalla ei ollut huomauttamista ohjelmaan.

19 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon tuotannon aikaisen SSOP/SOP-ohjelman. Laitoksen edustaja esitteli ohjelman. Tarkastajalla ei ollut huomauttamista ohjelmaan.

20 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon SSOP/SOP-ohjelman toteuttamisesta ennen tuotannon aloittamista laadittua kirjanpitoa. Laitoksen edustaja esitteli kirjanpitoa. Tarkastajalla ei ollut huomauttamista kirjanpitoon.

21 Tarkastaja pyysi laitoksen edustajaa esittelemään teurastamon SSOP/SOP-ohjelman tuotannon aikaisesta toteuttamisesta laadittua kirjanpitoa. Laitoksen edustaja esitteli kirjanpitoa. Tarkastajalla ei ollut huomauttamista kirjanpitoon.

22 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon ennen tuotannon aloittamista laaditun SSOP/SOP-ohjelman. Laitoksen edustaja esitteli ohjelman lyhyesti ja keskittyi lähinnä niihin kohtiin ohjelmassa missä kohtaan se eroaa teurastamon vastaavasta ohjelmasta. Tarkastajalla ei ollut huomauttamista ohjelmaan.

23 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon tuotannonaikaisen SSOP/SOP-ohjelman. Laitoksen edustaja esitteli ohjelman lyhyesti ja keskittyi lähinnä niihin kohtiin ohjelmassa missä kohtaan se eroaa teurastamon vastaavasta ohjelmasta. Tarkastajalla ei ollut huomauttamista ohjelmaan.

24 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon SSOP-ohjelman toteuttamisesta ennen tuotannon aloittamista laadittua kirjanpitoa. Laitoksen edustaja esitteli kirjanpitoa. Tarkastaja halusi nähdä erityisesti ne kohdat kirjanpidosta, jossa oli havaittu jotain puutteita pesutuloksessa ja, kuinka ne oli korjattu. Laitoksen edustaja näytti myös laitoksessa käytössä olevan epäkohtalomakkeen ja kertoi, kuinka sitä käytetään. Tarkastajalla ei ollut huomauttamista kirjanpitoon tai esitettyyn lomakkeeseen.

25 Tarkastaja pyysi laitoksen edustajaa esittelemään leikkaamon SSOP-ohjelman tuotannon aikaisesta toteuttamisesta laadittua kirjanpitoa. Laitoksen edustaja esitteli kirjanpitoa. Tarkastajalla ei ollut huomauttamista kirjanpitoon.

26 Tarkastaja pyysi laitoksen edustajaa esittelemään salmonellavalvontaohjelman. Laitoksen edustaja esitteli ohjelman ja sen, kuinka paljon näytteitä tulee tänä vuonna ottaa. Hän kertoi myös, että kaikki tulokset tänä vuonna ovat olleet negatiivisia. Tarkastajalla ei ollut huomauttamista ohjelmaan.

Tarkastuskierros:

27 Tarkastaja tarkasti ensin leikkaamossa ennen tuotannon aloittamista tehtävän puhtaustarkastuksen tarkastamisen. Tarkastuksella ei tarkastettu koko leikkaamoa vaan tarkastuseläinlääkärin etukäteen valitsemat kohteet. Tarkastuksella havaittiin nauhaleikkaamon lamellinauhassa, kamarakoneen kuljettimessa sekä kinkkulinjan takareunassa vähän lihajätettä. Laitoksen edustajat tekivät heti kaikki tarvittavat korjaavat toimenpiteet. Tarkastuksella havaittiin myös muutama kulunut nauha. Laitoksen edustajat kertoivat, että uudet nauhat on tilattu ja milloin ne on tarkoitus asentaa. Laitoksen edustajat tekivät kaikki tarvittavat korjaavat toimenpiteet välittömästi ja tarkastuseläinlääkäri ei havainnut heidän toiminnassaan huomauttamista. Tarkastuseläinlääkärit seuraavat viikkovalvonnassa tarkastuksessa havaittuja epäkohtia useammin ja, että seurantaan jääneet kohteet korjataan mahdollisimman nopeasti.

28 Seuraavaksi tarkastaja tarkasti teurastamossa ennen tuotannon aloittamista tehtävän puhtaustarkastuksen tarkastamisen. Tarkastuksella ei tarkastettu koko teurastuslinjaa vaan tarkastuseläinlääkärin etukäteen valitsemat kohteet. Peräpora-automaatissa sekä avausviillon tekevässä automaatissa oli rasvauksesta jäänyttä öljyä, josta laitoksen edustaja huomautti siivousliikkeen edustajia. Siivousliikkeen edustajat tekivät tarvittavat korjaavat toimenpiteet välittömästi. Halkaisukoneen yläpuolinen katto oli kostea ja siinä oli havaittavissa mahdollisesti homepilkkuja, josta tarkastaja huomautti. Laitoksen ja siivousliikkeen edustajat ryhtyivät välittömästi korjaaviin toimenpiteisiin. Laitoksen edustajat tekivät kaikki tarvittavat korjaavat toimenpiteet välittömästi ja tarkastuseläinlääkäri ei havainnut heidän toiminnassaan huomauttamista. Tarkastuseläinlääkärit seuraavat viikkovalvonnassa tarkastuk-

sessa havaittuja epäkohtia useammin ja, että seurantaan jääneet kohteet korjataan mahdollisimman nopeasti.

29 Tarkastaja tarkasti yhden ruhovaraston siisteyden ja rakenteiden kunnon sekä varastossa olevia ruhoja. Tarkastaja kysyi ruhovarastojen lämpötilasta ja hänelle selvitettiin että lämpötilanvalvonta ruhovarastossa on automaattinen ja että jokaisessa ruhovaraston osassa on myös perinteinen lämpömittari. Tarkastajalla ei ollut asiaan huomauttamista eikä ruhovaraston siisteyteen tai kuntoon.

30 Tarkastaja tarkasti E- *coli* näytteenoton asianmukaisuuden yhdessä ruhovarastossa. Laboratorion edustajat ottivat näytteet kahdesta ennalta arvotusta sian ruhosta. Tarkastajalla ei ollut huomauttamista näytteenottoon.

31 Tarkastaja tarkasti kahden sosiaalitilan siisteyden ja kunnon. Tarkastaja ei havainnut huomauttamista niiden kuntoon tai siisteyteen.

32 Tarkastaja tarkasti teurastamon tuotannon aikaista toimintaa. Tarkastaja tarkasti loppupuhdistuspisteessä laitoksen työntekijöiden tekemää ruhojen puhtaustarkastusta. Hänellä ei ollut huomauttamista ruhojen tarkastukseen. Tarkastaja halusi vielä, että laitos tarkastaa valon kirkkauden lux-mittarin avulla loppupuhdistuspisteessä. Tulokset olivat minivaatimusten yläpuolella eikä tarkastajalla ollut huomauttamista asiaan.

33 Tarkastaja tarkasti lihantarkastajien suorittaman post mortem-tarkastuksen asianmukaisuuden. Hänellä ei ollut huomauttamista heidän suorittamaan tarkastukseen.

34 Tarkastaja tarkasti sivuraiteen toimintaa. Tarkastuseläinlääkäri selitti hänelle sivuraiteen toimintaprosessia. Tarkastajalla ei ollut huomauttamista toimintaan.

35 Tarkastaja teki tarkastuskierroksen navetassa ja seurasi eläinten tainnutukseen ajoa sekä tainnutusta. Tarkastajalla ei ollut huomauttamista eläinten tainnuttamiseen. Lopuksi hän vielä tarkasti, kuinka eläimiä käsitellään navetassa. Hänellä ei ollut myöskään huomauttamista eläinten käsittelyyn.

Tarkastuseläinlääkäreiden toiminta; valvontasuunnitelman seuranta-aiheiden tarkastaminen

36 Tarkastaja totesi loppukokouksessa, että kaikki vuoden 2009 USDA:n auditoinnilla tehdyt havainnot epäkohdista on nyt korjattu.

Valvonnan arviointi

37 Tarkastuseläinlääkärin esittelemät viikkovalvontasuunnitelma ja -kirjanpito olivat Eviran ohjeen (19002/4) mukaisia. Tarkastajalla ei ollut myöskään huomauttamista niihin.

38 Tarkastuseläinlääkärit ovat kirjoittaneet Eviran ohjeen (19002/4) mukaisesti epäkohtaraportteja eikä niiden kirjoittamisessa havaittu huomauttamista. Tarkastajalla ei ollut myöskään huomauttamista niihin.

39 Tarkastuseläinlääkärin esittelemään ante mortem kirjanpitoon ei ollut huomauttamista. Tarkastajalla ei ollut myöskään huomauttamista kirjanpitoon.

40 Tarkastuseläinlääkärin toiminta tarkastustilanteissa, tarkastuseläinlääkärin laitoksen edustajille esittämät kysymykset ja huomautukset todettiin asianmukaisiksi.

41 Tarkastuseläinlääkärin tulee kiinnittää huomiota, että päivän valvontasuunnitelma aiheet kirjoitetaan auditointisuunitelman mukaisesti tarkastusraporttiin ja muut auditoinnilla käsitellyt aiheet kirjoitetaan oikeisiin kohtiin tarkastusraportissa, muuten tarkastuseläinlääkärin kirjoittama tarkastusraportti oli kirjoitettu asianmukaisesti ja se noudatti Eviran tarkastusraportista annettuja ohjeita (19002/4).

Seuraavalla auditoinnilla seurattavat asiat

42 Tarkastuseläinlääkäreiden toiminnassa ei auditoinnilla havaittu sellaisia epäkohtia, jotka edellyttäisivät seurantaa.

43 Seuraavalla auditoinnilla auditoidaan uudestaan sivutuoteohjelma ja sivutuotteiden käsittely, koska näitä aiheita ei auditoitu tämän auditoinnin yhteydessä.

44 Seuraavilla auditoinneilla auditoidaan myös, kuinka tarkastuseläinlääkärit ovat seuranneet USDA:n tarkastajan havaitsemia epäkohtia laitoksen toiminnassa, kirjanpidoissa tai ohjelmissa.

Laitoksen vaatimustenmukaisuus ja vientiehtojen täyttäminen

45 Tarkastuksella tarkastaja havaitsi joitain puutteita leikkaamon aamutarkastuksen suorittamisessa sekä leikkaamon toiminnan aikaisessa toiminnassa. Samoin teurastamon HACCP-ohjelmassa sekä siihen liittyvissä kirjanpidoissa hän havaitsi muutamia puutteita. Tarkastajan mielestä kuitenkin laitoksen edustajat osasivat tehdä korjaavat toimenpiteet oikein tarkastuksen aikana. Samoin hänen mielestään kaikki vuoden 2009 USDA:n tarkastuksella havaitut puutteet oli korjattu. Tämän vuoksi hän oli sitä mieltä, että laitos täyttää riittävässä määrin sille asetetut vaatimukset ja vientiehdot tarkastettujen osa-alueiden osalta.

Evira

ELINTARVIKETURVALLISUUSVIRASTO
Lihantarkastusyksikkö
Tarkastuseläinlääkäri Irmeli Sippola
PL 900, 60060 Atria

Päiväys 14.6. 2012 **Dnro** 691/0921/2012

USA:n vientiin hyväksytyn laitoksen tarkastusraportti

Laitoksen nimi:	Atria Oy, Nurmo
Laitoksen hyväksymisnumero:	22
Tarkastuspäivämäärä:	12.6.2012
Tarkastuksen suorittaja:	Tarkastaja Nader Memarian, USDA Tarkastuseläinlääkäri Irmeli Sippola
Tarkastuksessa läsnä:	Ylitarkastaja Sirpa Kemilä, EVIRA, Ylitarkastaja Tuomas Haltiala, EVIRA, Tarkastuseläinlääkäri Marja Fossi, ISS:n päällikkö Minna Vornanen, ISS:n työnjohtaja Janne Keskitalo, Lihalinjan johtaja Markku Hirvijärvi, Teurastamopäällikkö Pekka Honkaranta, Tuotantopäällikkö Pekka Honkaranta, Teurastamon esimies Jari Kujanpää, Leikkaamon esimies Rainer Roukala, Hygieniapäällikkö Vesa Mäntynen, Omavalvoja Tiina Kinnunen
Tiedoksi:	Elintarviketurvallisuusvirasto; A-Sikateurastamo Oy: Markku Hirvijärvi, Tuomas Viita, Pekka Honkaranta, Jari Kujanpää, Marko Talso, Petri Ala-Välkkilä, Saila Huhtala, Rainer Roukala, Ville Pohto, Vesa Mäntynen, Tiina Kinnunen
Allekirjoitus:	

1.1 Päivän valvontasuunnitelman aiheet:

Leikkaamossa ja teurastamossa ennen tuotannon alkua tehtävä aistinvarainen SSOP/SOP-siivoustarkastus;
Teurastamon ja leikkaamon tuotannon aikaisen SSOP/SOP-ohjelman ja kirjausten tarkastus;
Leikkaamossa ja teurastamossa tuotannon aikana tehty SSOP/SOP-tarkastus;
Teurastamon HACCP-ohjelman ja kirjausten tarkastus; Leikkaamon HACCP-ohjelman ja kirjausten tarkastus
Lähtötarkastuksen tekemisestä (preshipment) kirjatun ohjelman ja kirjausten tarkastus;
Salmonellavalvontaohjelman tarkastus; E.coli-näytteiden ottamisesta tehdyn ohjelman, näytteiden ottamisen asianmukaisuuden ja kirjausten tarkastus.

1.2 Valvontasuunnitelman seuranta-aiheet: Ei seuranta-aiheita.

1.3 Valvontasuunnitelman lisäaiheet: Ei lisäaiheita.

1.4 Auditointisuunnitelman seuranta-aiheet: Ei lisäaiheita.

1.5 Auditointisuunnitelman lisäaiheet: Ei lisäaiheita.

Tarkastuksessa tehdyt havainnot

2.1 Leikkaamossa ennen tuotannon alkua tehtävä aistinvarainen SSOP/SOP-siivoustarkastus,

Leikkaamon esimies tarkasti nauhaleikkaamon paloittelualueen, 0- ja 1-linjojen rakenteet ja järjestelypään sekä laatikkoleikkaamon reunalinjan ja päätykäytävän. Sisääntulon jälkeen USDA:n tarkastaja havaitsi linjan 3 yläpuolisen ilmastointiritilän alareunassa roikkuvan lihakokkareen. Alueella ei ollut kondenssia. Ritilä puhdistettiin heti.
Ruhojen sisääntulon ovipleksit ja sirkkelin terän viereiset rakenteet kuivattiin.
Karkeapaloittelunauha, laatikkoleikkaamon leveä paloittelunauha ja 0-linjan alanauha olivat kuluneet. Uudet nauhat oli tilattu ja esimies kertoi vaihtoaikataulun.
Nauhaleikkaamon lamellinauhassa oli leimausmusteen aiheuttamaa värjäytymää ja reunassa lihajätettä. 0-linjan kamarakoneen kuljettimessa oli vähän lihajätettä. Kinkkulinjan alanauhan takareunassa oli lihajätettä, jonka USDA:n tarkastaja havaitsi. Esimies pesetti uudestaan kaikki likaiset kohteet.
Laatikkoleikkaamon vastaanottotarkastajan pöytä kuivattiin ja vieressä ollut, seinään koskenut puhallin puhdistettiin. Nostajan tulirakenteissa ja ohjaimissa ollut kosteus kuivattiin.
Sisäfileen puhdistuspöydässä ja kolmessa 0/1-linjan pöytälevyssä oli pieniä mustia piskoja, jotka esimies puhdistutti.

Siivouslikkeen työntekijä pesi viipymättä kaikki likaisiksi havaitut kohteet uudestaan. Esimies tarkasti ja hyväksyi korjaavat toimenpiteet ennen tuotannon alkua.

2.2 Teurastamossa ennen tuotannon alkua tehtävä aistinvarainen SSOP/SOP-siivoustarkastus

Teurastamon esimies tarkasti teurastamon puhtaan alueen auditoinnin aikana, ennen tuotannon alkua. Peräpora-automaatissa ja avausviillon tekevässä automaatissa oli koneiden rasvauksesta levinnyttä öljyä, jotka esimies pesetti siivousliikkeen työntekijällä. Suolistusrobotin ovien rasvapiskot pyyhittiin ennen tuotannon alkua. Päänkatkaisuautomaatin terissä oli vähäistä ruostevärjäytymää, joka pyyhittiin puhtaaksi. Halkaisukoneen yläpuolinen kattoalue oli homepilkuissa ja tiivisteet värjäytyneet. Alue hangattiin puhtaaksi ja silikonit uusittiin ennen tuotannon alkua.
Elinkuljettimessa olleet rasvavalumajäljet puhdistettiin pyyhkimällä. Suolistustason viereisten tukipalkkien pesuroiskeet pyyhittiin puhtaiksi.
Puukkopesureissa olleet puukot ja kasetit olivat puhtaat. Tarkastetut linjarakenteet olivat puhtaat. Osastolla ei todettu kondenssia.

Siivousliikkeen työntekijä pesi viipymättä kaikki likaisiksi havaitut kohteet uudestaan. Esimies tarkasti ja hyväksyi toimenpiteet ennen tuotannon alkua.

Siivouksen taso oli rakenteiden osalta hyvä. Pesupuutteita todettiin kolmen automaatin rakenteiden puhdistuksessa ja yhden automaatin yläpuolisissa kattorakenteissa. Tuotekontaktipinnat oli pesty moitteettomasti. Esimiehen teettämät korjaavat toimenpiteet todettiin riittäviksi.

2.3 Teurastamossa ennen tuotannon alkua ja tuotannon aikana toteutettava SSOP/SOP-ohjelma ja kirjaukset

Hygieniapäällikkö esitteli SSOP/SOP-preoperationaalisen ohjelman kokonaan englanniksi. SSOP/SOP-operationaalinen tarkastusohjelma ja kondensaatiota koskevat poikkeamaohjeet käytiin läpi. Tarkastaja tahtoi nähdä pesuaineiden käyttöturvallisuustiedot ja hyväksymiset. Sikalinjan ja Tuorelihan pesuaineluettelo oli päivitetty 7.6.12.
Tarkastaja katsoi ohjelmien kirjauksia maalis-toukokuun väliseltä ajalta.
Teurastamon aamutarkastuksesta tehdyt kirjaukset tarkastettiin ja todettiin asianmukaisiksi.
Tarkastaja katsoi lisäksi desinfektioaltaiden lämpötilaseurantakirjaukset.
Tarkastajalla ei ollut huomautettavaa ohjelmista tai kirjanpidoista.

2.4 Leikkaamossa ennen tuotannon alkua ja tuotannon aikana toteutettava SSOP/SOP-ohjelma ja kirjaukset

Leikkaamon SSOP/SOP-ohjelmien toteutuksessa olevat eroavuudet teurastamon tarkastusohjelmiin selvitettiin. Tarkastaja etsi leikkaamon kirjauksista erityisesti kohteita, joissa oli puututtu aamutarkastuksessa todettuihin epäkohtiin. 31.5.12 oli kirjattu SSOP-poikkeamaraportti leikkaamon ovien puhtaudesta. Tarkastaja kysyi raportin täyttöohjeista ja todentamisesta.
6.6.12 oli kirjattu SSOP-poikkeamaraportti rakenteisiin koskeneista kinkuista, jonka korjauskirjaukset ja verifioinnin tarkastaja totesi asianmukaiseksi.
Tarkastaja tahtoi tietää, onko kirjauksia kondensaatiosta. Niitä ei löydetty selaamalla. Omavalvojan mukaan edelliset kirjaukset ovat kesältä 2011. Sen jälkeen ilmastoinnin korjaukset ovat poistaneet ongelmat.
Hygieniapäällikkö kävi läpi 10.5.12 päivitetyissä leikkaamon työohjeissa kuvatut poikkeamaohjeet likaantuneiden lihojen edellyttämistä korjauksista.
Tarkastajalla ei ollut huomautettavaa ohjelmista tai kirjanpidoista.

2.5 Leikkaamossa tuotannon aikana toteutettava SSOP/SOP-ohjelma

Lihalinjan johtaja teki tuotantohygieniaseurantaa leikkaamon esittelykierroksen aikana. Sisääntulo- ja paloittelualue oli asianmukaisessa järjestyksessä klo 10:30. Laatikkoleikkaamon tyhjän työpisteen 25 kohdalla johtaja havaitsi kuitenkin useita lihalaatikoita, joissa oli pieniä, mustia hippuja. Hiput todettiin lamellinauhan paloiksi. Leikkaamon toiminta keskeytettiin, tuotelaatikot tarkastettiin ja suojattiin, tyhjät laatikot ohjattiin pesuun.
Tarkastaja kysyi puukkojen teroitushuoneesta, mitä oven takana oli. Huoneessa ei käyty. Järjestelypään puhdistuspöydällä tehtävän puhdistuksen toimintatapa selvitettiin USDA:n tarkastajalle.
Selkäpaloilla oli ylitäysi molla, jonka lihalinjan johtaja opasti heti vajentamaan. Kamara-alueella oli myös liian täysi nahkamolla. Esimies haki tilalle tyhjän mollan.
Lajitelmavarastossa kaikki tuotteet olivat peitettyinä. Tarkastaja katsoi ja pyysi selvittämään S-I –lajitelman etikettitiedot.
Lavaamossa oli peittämätön selkäpalamolla; samassa tilassa käytetään puulavoja. Lihat ohjattiin viipymättä rehulle. Työntekijä opastettiin.
Leikkuulinja 3:lla oli ylitäyttöä. Esimies kehotti hidastamaan paloittelua.
Lautasalueella tarkastettiin USA:han vietävää tuotetta.
Paloittelualueelle palattaessa todettiin, että työntekijä oli nostanut kahden ruhon puolikkaat samanaikaisesti puhdistuspöydälle ja aiheuttanut ruhojen lisäkontaminoitumisen. Esimies opasti työntekijälle välittömät korjaavat toimenpiteet. Sisääntuloalueella oli vastaanottotarkastuksen ohi päässyt ruho, jossa USDA:n tarkastaja ensimmäisenä havaitsi suolen sisältöä pään alueella. Tarkastuseläinlääkäri totesi, että mahalaukun sisältö oli noncompliance: SSOP-virhe leikkaamossa ja HACCP:n poikkeama teurastamossa.
USDA:n tarkastaja havaitsi viimeistelemättömän ilmastointihormin läpimenon puhdistusalueen yläpuolella.

Laitoksen työntekijöiden tekemät välittömät korjaavat toimenpiteet olivat asianmukaiset. Seurantaan jääville kohteiden osalta seurantaa ja valvontaa tihennetään.

2.6. Teurastamossa tuotannon aikana toteutettava SSOP/SOP-ohjelma

Teurastamon työntekijöiden toiminnassa ei ollut huomautettavaa. Sivuraiteella USDA:n tarkastaja kiinnitti huomiota siihen, että laitoksen työntekijä ei saa koskea pidätettyihin ruhoihin ennen kuin tarkastuseläinlääkäri on ne tarkastanut.
Aamutarkastuksen jälkeiset korjaukset varmistettiin tehdyiksi.

2.7 Teurastamon HACCP-ohjelma

Omavalvoja esitti 25.5.12 päivitetyn HACCP-ohjelman. Vaarojen arvioinnissa ei oltu perusteltu mahdollisia biologisia vaaroja, muuta kuin eläinten kasvatusvaiheessa, eläinten vastaanotossa ja lajittelussa, sekä sairaiden eläinten käsittelyvaiheessa. Seuraavat perustelut oli annettu pisto- ja peräsuolen imurointivaiheista. Pisteissä, joissa teurastustoimenpiteillä mennään nahan läpi, oli todetut, merkittävät vaarat perusteltu.
Vaarojen arviointipäätöksen perusteeksi tulee joka tuotantovaiheesta voida esittää tukevaa aineistoa - tai kirjata HACCP:n vaarojen arviointitaulukkoon päätöksen peruste. Perusteen tulee kohdistua kyseessä olevaan vaaraan. Siinä voidaan myös viitata eläinten vastaanotossa ja lajittelussa käytettyihin perusteisiin.

Tarkastaja huomautti seuranta-, todentamis- ja reinspektiolomakkeiden epätarkkuuksista: Seuranta-lomakkeessa ei ollut kohtaa ylimääräiselle seurannalle, jolla kriittinen piste varmistetaan saaduksi hallintaan.

Todentamislomakkeesta puuttui todentajan allekirjoituskohdasta päivämäärä- ja kellonaikamerkintä. Päivämäärä oli lomakkeen yläreunassa ja todentamisajat ruhojen osalta lomakkeessa. Reinspektio-asiakirjasta puuttui uudelleen tarkastuksen toteutusaika.
Kriittisen pisteen kuvauksesta puuttui selvitys, kuinka varmistetaan CCP:n saaminen hallintaan uudella monitoroinnilla.
HACCP:n kirjaukset olivat ohjelman mukaiset.

2.8 Leikkaamon HACCP-ohjelma

Leikkaamon HACCP-ohjelma ja kirjaukset todettiin vaatimusten mukaisiksi.

2.9 Lähtötarkastuksen tekemisestä (preshipment) kirjattu ohjelma

Preshipment-ohjelma ja kirjaukset todettiin vaatimusten mukaisiksi.

2.10 Salmonellavalvontaohjelma

Teurastamon ja leikkaamon 20.4.12 päivitetty salmonellavalvontaohjelma todettiin vaatimusten mukaiseksi. Näytemäärät todettiin Eviran lähettämän suunnitelman mukaisiksi. Kaikki näytetulokset olivat olleet nagatiivisia.

2.11 E.colinäytteiden ottamisen asianmukaisuus

Tarkastettiin Hannu Kangasmaan tekemä E.coli-näytteenotto. Toteutus oli ohjeen mukainen.

Havainnot ja epäkohdat, joiden johdosta tehtyjä toimenpiteitä seurataan tulevissa tarkastuksissa

3.1 Siivousohjelman tehostaminen nauhojen, laatikoiden ja pöytien osalta. Ylärakennepesujen ja SSOP-pintojen puhtauden seurannan tehostaminen. Seurataan viikkovalvontasuunnitelmien mukaisesti.
3.2 Kunnossapito-ohjelman tehostaminen. Seurataan viikkovalvontasuunnitelmien mukaisesti.
3.3 Sisääntulotarkastuksen ja sen seurannan tehostaminen. HACCP-palautteen antamisen varmistaminen.
3.4 Teurastamon HACCP-ohjelman vaarojen arvioinnin, seurantalomakkeiden ja kriittisen pisteen korjaavien toimenpiteiden tarkentaminen. Seurataan auditoinnin yhteydessä.

Laitoksen vaatimustenmukaisuus ja vientiehtojen täyttäminen

4. Tarkastuseläinlääkäri arvioi, että laitos täyttää riittävässä määrin sille asetetut vaatimukset ja vientiehdot tarkastettujen osa-alueiden osalta. Tarkastuseläinlääkäri antoi tarkastusta koskevat huomiot tiedoksi laitokselle 13.6.12 viikkovalvontaraportissa, ja 15.6.12 tarkastuskertomuksessa.