



United States Department of Agriculture

Food Safety and
Inspection Service

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JUL 28 2015

Dr. Eva-Riitta Wirta
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Dear Dr. Wirta:

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Finland's meat inspection system from March 4 through March 17, 2015. 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.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director, International Audit Staff, Office of Investigation, Enforcement and Audit at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at international.audit@fsis.usda.gov.

If you have any questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

FINLAND

MARCH 4 - 17, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 23, 2015

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 4 – 17, 2015. The purpose of the audit was to determine whether Finland's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled. Finland currently exports raw intact pork to the United States.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Statutory Authority and Food-Safety Regulations (Inspection System Operation and product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs and Government Microbiological Testing Programs.

The significant audit findings are as follows:

- The CCA was using non-government employees (establishment employees) to conduct post-mortem inspection examinations when short staffed. This is indicative of a serious conflict of interest between the CCA and the establishment at which it provides inspection.
- The CCA is not adequately assessing the corrective actions proposed by establishments (immediate and preventive) with respect to their sanitation performance standards (SPS) related to facility and equipment maintenance.

During the audit exit meeting, the CCA committed to addressing the preliminary audit findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once it receives them and base future equivalence verification activities on the information provided.

In response to FSIS audit findings presented at the audit exit brief, FSIS has received a letter from the Finnish Food Safety Authority (EVIRA) (Reference attached letter United States -audit 4.-3.17.2015 titled MAARAYS LIHANTARKASTAJIEN SIJAISISTA). The letter states that EVIRA has halted the practice of using establishment employees to conduct post-mortem inspection duties and will only use official inspection personnel to conduct all related inspection duties. Additionally, EVIRA issued a Notice of Intent to Delist (NOID) on March 16, 2015, to the two audited establishments, which are the only establishments certified to export to the United States, related to issues identified during the course of the audit. The FSIS auditor was informed that EVIRA would conduct a targeted follow-up audit to verify the implementation of corrective actions taken by the establishments. EVIRA promised to address the audit findings with inspection personnel during a training session in May 2015.

FSIS requests that the CCA provide a detailed response for each of the identified findings within 60 calendar days of receipt of this report. The CCA's initial response during the audit was satisfactory. Specifically, FSIS requests further information and evidence of corrective actions from Finland as to how they plan to provide inspection coverage when a staffing shortage occurs at establishments long-term, as well as, the results of its follow-up audit and training session.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Finland's food safety system from March 4 to March 17, 2015. The audit began with an entrance meeting held on March 4, in Helsinki, with the participation of representatives from the Central Competent Authority (CCA) – The Finnish Food Safety Authority (EVIRA) and an auditor from the FSIS.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled.

To meet this objective, FSIS applied a risk-based procedure that included analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, port-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe, in addition to information obtained directly from the CCA, through a self-reporting process.

The FSIS auditor was accompanied throughout the entire audit by EVIRA representatives from headquarters and local inspection offices. Determinations concerning program effectiveness focused on the CCA's performance within the following six equivalence components, upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis Critical Control Point (HACCP) System, (5) Government Chemical Residues Control Programs, and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, and two local inspection offices. The FSIS auditor evaluated the implementation of management control systems that are in place to ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

At the time the FSIS audit plan was originally developed, three certified establishments were eligible to export to the United States. In February 2015, FSIS received communication from the CCA reducing the number to two certified establishments. EVIRA decertified one slaughter and processing establishment as it will no longer export to the United States. Consequently, FSIS audited two pork slaughter and processing establishments, certified to export raw pork products to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

The Chemical and Toxicology Research Unit a government laboratory that conducted chemical analyses related to United States exports, and Atria Oyj Microbiological Laboratory a private laboratory that conducted microbiological analyses related to United States exports were both audited in order to verify their ability to provide adequate technical support to Finland's inspection system.

A summary of specific audit locations is provided in the following table:

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Helsinki
	Local	2	• Forssa • Nurmo
Laboratories		2	• The Chemical and Toxicology Research Unit (Helsinki) - Government • Atria Oyj Microbiological Laboratory (Nurmo) - Private
Establishments: Pork Slaughter and Processing		2	• Forssa • Nurmo

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Finland's inspection system for meat products included: (1) all applicable legislation originally determined by FSIS as equivalent as a part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

Additionally, Finland has equivalence determinations in place for the following:

- The CCA may allow either fully trained establishment or government employees, to take samples applicable to generic *E. coli* and *Salmonella* testing programs.
- Testing for *Enterobacteriaceae* and total viable count in lieu of testing for generic *E. coli* is acceptable for all European Union (EU) exporting countries.
- The use of an alternative laboratory testing method ISO 6579 - 2002 (modified) for *Salmonella* by Finland is acceptable. In addition, FSIS has granted Finland equivalence for use of *Salmonella* methods ISO 6579:1993 and NMKL 71 (dated 1999).
- Finland's use of methods NMKL 147:1993 for generic *E. coli* and NMKL 144 (dated 2005) for *Enterobacteriaceae* is acceptable.
- The use of private laboratories for the analysis of official samples is acceptable.

The evaluation of each component of Finland's meat inspection system included a review of Finland's answers to FSIS' Self-Reporting Tool (SRT), documentation submitted by the CCA as

support for their responses to the SRT, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and in the audited establishments.

III. BACKGROUND

Finland is eligible to export pork products to the United States. From October 1, 2012 to January 30, 2015, Finland has exported 3,948,813 pounds of raw intact pork products; of this volume, 2,546,078 pounds of the product received types of inspection (TOI) beyond certification and labeling verification at the POE. Of this volume, no product was rejected for food safety reasons. Finland exports only raw intact pork to the United States.

FSIS last audited Finland in 2012 and reported no systemic findings. The FSIS final audit reports for Finland's food safety system are available on the FSIS' website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

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

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

The FSIS auditor verified that the inspection system was organized and administered by the national government of Finland, which provided standards equivalent to those of the Federal system of meat inspection in the United States. Finland is a part of the EU and governed by the EC. There have been no major changes in the CCA's organizational structure since the last FSIS audit. The Ministry of Agriculture and Forestry (MAF) is responsible for the general planning and supervision of food and veterinary controls. The EVIRA operates under the support of MAF, and is the agency that serves as the CCA to administer the Finnish meat inspection system. EVIRA is responsible for directing, planning, steering, and carrying out food safety and animal health and welfare controls. *Law 617 of 1997*, as amended by *Law 299 of 2006*, designates EVIRA as the Competent Authority and as a control body. The CCA oversees the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by importing countries.

The CCA's authority to enforce inspection laws comes from *EC Regulation No. 178/2002* of the European Parliament and of the Council of 28 January 2002 defining the general principles and requirements of food law, establishing the European Food Safety Authority, and defining procedures in matters of food safety. EC regulations are the primary overarching laws for regulating meat inspection. Finland is responsible for enforcing and ensuring that adulterated or

misbranded products are not exported to the United States through their national legislation and implementing regulations. Finland has issued national legislation 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 CCA has the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States.

The CCA has one central (Headquarters) office headed by EVIRA's Chief Veterinary Officer (CVO) and is organized and executed by three (3) specific departmental offices within:

1. Control Department - oversees Animal Health and Welfare, Food Hygiene, Import, Export and Organic Control, Meat Inspection, and Product Safety,
2. Research and Laboratory Department - oversees Chemistry and Toxicology, Food and Feed Microbiology, Pathology, Risk Assessment, Veterinary Bacteriology, and Virology, and
3. Administrative Department - oversees Communications, Finances, Human Resources, IT Management, Legal Affairs and Planning and Direction.

A Senior Officer heads each of EVIRA's departments. The Import, Export and Organic Control Unit (IEOCU), a unit under the Control Department, represents the first level of the inspection system and has direct authority over the establishments that are certified for export to the United States. The head of IEOCU issues guidelines and instructions that deal with the frequency of supervisory reviews; the procedures for registration, approval, conditional approval or suspension, and withdrawal of approval of regulated establishments; the verification of the microbiological sampling; the performance of official inspection tasks; and the scope and method of carrying out the National Residue Control Plan in accordance with *EC Directive 96/22* and *96/23*. The CCA disseminates inspection information related to the regulatory and administrative affairs electronically via email, telephone, and hard copy to inspection personnel and establishments certified to export product to the United States. The in-plant inspection represents the second level of inspection and is headed by the Veterinary Officer (VO).

The FSIS audit of the CCA Headquarters included an examination of their oversight activities, including audits of establishments conducted by the Control Department. These audits represent supervisory reviews. In addition, FSIS examined enforcement activities, verification activity reports, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

EVIRA oversees the functions of the Control Department responsible for regulating the meat industry and certifying establishments to export meat products to the United States. The Control Department of the EVIRA is responsible for the official certification or decertification of, and maintaining the official list of, establishments eligible to export to the United States. The IEOCU under the Control Department is responsible for conducting supervisory reviews in establishments certified as eligible to export to the United States.

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 to export and the actions taken by government officials at each step of the approval process. The CCA has the sole authority to grant final certification of a new establishment or to permit an existing United States-certified establishment to maintain its eligibility to export to the United States.

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 based on observations made by inspection personnel for HACCP, Sanitation Standard Operating Procedures (SSOP), or other non-compliances. The Notice of Intent to Delist (NOID) letter has the same 30-day time frame for correcting the non-compliance. If an establishment is given more than three warning letters during a period of 2 years, then the establishment’s export approval will be removed. In addition, EVIRA’s Guideline 18511/1 describes the official veterinarians’ responsibilities regarding the official process for suspension, delisting, and relisting of certified establishments.

The FSIS auditor verified elements of *Food Act*, Section 14 - “*Application Procedure for Approval of Food Premises*” and Section 61 “*Cancelling the Approval of Food Premises.*” These documents include a registration form, initial approval determinations, and certification documents maintained by government officials at the CCA headquarters including sections that correspond to the sanitation requirements, 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. These documents corresponded to an establishment that EVIRA decertified as it will not export to the United States in February 2015. The auditor observed that inspection officials had reviewed the documents submitted by the establishments, audited the facilities and evaluated their ability to meet regulatory requirements prior to granting renewal of certification to export meat to the United States.

The Finnish enforcement strategies in place are based on EU regulation 882/2004, *Finnish Food Act* and *EVIRA’s Guideline 18511/1*. The *Finnish Food Act*, Chapter 10, explains penalties for health offences violating the provision of this Act. FSIS verified that the CCA prevents fraud or misuse of export health certificates by issuing export health certificates on secure watermarked paper.

The CCA maintains adequate administrative and technical support to operate its laboratory system. The CCA provides oversight for the government and private laboratory systems. Government and private laboratories are accredited by the Finnish Accreditation Service (FINAS) annually for ISO 17025 accreditation. FINAS is identified by *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 audits these laboratories annually. The CCA, as part of its oversight responsibilities, conducts annual reviews and audits of the laboratories, which are responsible for testing of product destined for export to the United States. 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 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 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 audited the government 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*. FSIS also audited the Atria Oyj Microbiological Laboratory, a private laboratory in Nurmo. The FSIS auditor verified that each laboratory was accredited according to ISO 17025. The FSIS auditor reviewed the CCA, FINAS and third-party review and audit documents generated for the previous year at CCA Headquarters and at the audited laboratories. No concerns arose as the result of these reviews. FSIS' on-site audit did not identify any issues with the government chemical laboratory. However, the FSIS auditor did identify two findings associated with the private microbiological laboratory's quality management system (ISO 17025) that were not consistent with current FSIS policy for microbiological laboratories:

- The laboratory has no mechanism in place to monitor the incubators in use on the weekend and off days. The laboratory monitors the temperature of the laboratories incubators once daily (manually) during the workweek (Monday-Friday) only when employees are working.
- The laboratory's temperature parameters associated with the storage of samples and media received is set at 2^o - 8^o C (+2^o C). The media contained in the refrigeration unit list the storage temperature parameters at 2^o - 8^o C. Therefore, the media could be stored at 10^o C, which is 2^o C over the media's required temperature.

The on-site audit findings indicate a need for the CCA to improve its oversight activities concerning the above findings related to the private microbiological laboratories quality management system.

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. 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 practical training on the slaughter line and theoretical class work, after which they must pass specific examinations before being qualified to work in export meat establishments. The CCA in cooperation with Finnish Meat Research Institute (FMRI) provides these training courses.

The FSIS auditor verified that since the last FSIS audit in 2012, the CCA has provided ongoing training programs intended to ensure that inspection officials - both veterinary officers and non-veterinary inspectors - are aware of specific inspection requirements that pertain to Finland's meat export to the United States. Training records indicated that training is conducted routinely with an emphasis on requirements to export to the United States. In addition, the auditor observed in-plant inspection personnel while they were conducting their inspection activities and

laboratory personnel performing daily activities. The FSIS auditor has verified that both in-plant inspection and laboratory personnel have attended the ongoing training and have sufficient training to perform their inspection activities.

The CCA operations are funded by the government budget, in accordance with the *Food Act 23/2006, Chapter 8*. Inspection personnel at establishments certified to export meat to the United States are required to be full-time government employees. Finland's previously submitted documentation through the SRT identified that EVIRA assigns inspection personnel to establishments eligible to export products to the United States (warrant of appointments of the inspection personnel), and that the inspection personnel assigned to establishments certified to export to the United States are employees of the national government. The government retrieves the costs of inspection activities from the establishments.

The FSIS auditor conducted a document review of EVIRA government paid employee inspection rosters and recorded accountable time worked by inspection personnel at the establishment and interviewed EVIRA in-plant inspection VO to verify that all inspection employees are employed by EVIRA. The FSIS auditor identified that not all on-line inspection personnel that conduct post-mortem inspection are government-paid employees as defined in *Statutes no. 38/EE/2006*.

EVIRA allows for the practice of Supervisory Official Veterinarians at establishments to request the temporary employment of establishment employees to conduct post-mortem inspection of the heads and viscera for EVIRA when there is a short-term shortage of EVIRA auxiliaries (inspectors) for post-mortem inspection, and there is no available alternative to staff the slaughter inspection line.

This practice of using establishment employees to conduct post-mortem inspection leads to a direct conflict of interest between the CCA and the establishment for which they provide regulatory verification.

The CCA took immediate action to address this deficiency by halting the practice when it was initially identified by FSIS during the audit of the first establishment. The CCA later issued a letter on March 16, 2015, to the certified establishments that halted the practice of using establishment employees to conduct post-mortem inspection duties. The CCA instructed the VO that they would only use official inspection personnel to conduct all related inspection duties.

In conclusion, the audit determined that the Finnish government organizes and administers the country's meat inspection system, and that CCA officials are assigned to enforce laws and regulations governing production and export of meat at certified establishments. However, the FSIS auditor identified several findings related to the Government Oversight during the establishment audits that require the CCA's attention. The on-site audit findings indicate a need for the CCA to discontinue the practice of using of non-government employees (establishment employees) to conduct post-mortem inspection when short staffed and to restructure its government oversight activities concerning the CCA's assignment of relief inspectors to certified establishments. In addition, the CCA needs to improve its oversight concerning quality management system of private microbiological laboratories.

During the exit meeting on March 17, 2015, FSIS received EVIRA's response to FSIS' preliminary audit findings. The response EVIRA provided was to implement immediate corrective actions for the short-term and a commitment for long-term prevention of recurrence of these findings.

FSIS requests that the CCA provide a detailed response for each of the identified findings within 60 calendar days of receipt of this report. FSIS has requested information from Finland as to how it will provide inspection coverage when a staffing shortage occurs at establishments, as well as the results of its follow-up audit, verification activities, and training session.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and supervisory visits to official establishments.

The FSIS auditor verified that the CCA maintains regulatory authority as outlined in official legislation, regulations, and other instructions. Their authority is in accordance with the *EC Regulations 178/2002; 852/2004* on the hygiene of foodstuffs; *853/2004* describing specific hygiene rules for the food of animal origin; *854/2004* describing specific rules for the organization of official controls on products of animal origin intended for human consumption; *882/2004* on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; Decision *98/258/EC* on the conclusion of the Agreement between the European Community and the United States on sanitary measures to protect public and animal health in trade in live animals and animal products; and *Finland Food Act*.

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 described 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 FSIS auditor verified that the CCA provided inspection personnel at the two swine slaughter and processing establishments audited with the appropriate regulatory authority and direction to enforce requirements for Finland's food safety system governing meat products exported to the United States. FSIS accompanied the CCA inspection personnel and observed the performance of verification activities by the in-plant inspection personnel. The verification activities observed included ante-mortem inspection, humane handling and slaughter monitoring, post-mortem inspection, zero-tolerance verification of establishment's procedures for controlling of

feces, ingesta contamination, *Salmonella* and generic *Escherichia coli* (*E. coli*) sample collection, verification of pre-operational and operational sanitation verification procedures, HACCP verification activities, performance evaluation of on-line inspectors and supervisory reviews of establishments certified eligible to export to the United States. No concerns arose as the result of these observations.

The FSIS auditor verified through direct observation, on-site record reviews, and interviews that CCA ante-mortem inspection activities complied with EU and Finnish regulations in the two swine slaughter and processing establishments audited. These activities also met applicable portions of FSIS Directive 6100.1 "Ante-Mortem Livestock Inspection." The veterinarian reviewed the in-coming registration and identification document with each load/truck and observed all swine at rest and in motion in designated holding pens in order to determine whether they are fit for slaughter. There is a separate pen marked for examination of suspect animals at each establishment.

The CCA inspection officials are also responsible for verifying that operators comply with humane handling requirements that livestock is humanely handled and slaughtered, for which results are documented. 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 that if an animal were to be held overnight, feed would be provided. The FSIS auditor also observed in-plant inspection verification of humane handling procedures including the use of a carbon dioxide gas chamber, gas concentration, and its exposure time in order to render all animals insensitive to pain before being shackled or cut.

The FSIS auditor verified that written procedures are in place instructing inspection personnel how post-mortem inspection is to be performed, including visual inspection, palpation, and incision of relevant portions of the animal described in *EU Regulation 854/2004*. The FSIS auditor verified, through direct observation of inspection personnel and the review of CCA assessment documents, that inspection personnel followed the procedures outlined to conduct post-mortem inspection of heads, viscera, and carcasses. 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 part also met applicable portions of FSIS Directive 6100.2 "Post-Mortem Livestock Inspection."

The design of the post-mortem inspection stations, including the number of on-line inspectors also met United States' requirements. The presence of a veterinary inspector during post-mortem examination is mandated in *Chapter II of Appendix I of the Food Act*. The veterinary inspector is responsible for supervising on-line non-veterinary inspectors and post-mortem inspection activities including disposition of suspect carcasses and parts.

Dispositions of suspects during ante-mortem and post-mortem, and verification of acceptability of the final product, are the responsibility of the VO, who prepares daily post-mortem disposition reports to document his/her official control actions. Official veterinarians have legal authority to condemn carcasses. The FSIS auditor observed 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 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 and review of establishment's records, including SSOP, Sanitation Performance Standards (SPS), HACCP, and *Salmonella* and generic *E. coli* sampling techniques and records, in accordance with the CCA weekly inspection task plans outlined in Finnish document titled "*n vientiin hyväksytyjen laitosten viranomaisvalvonta.*"

The FSIS auditor specifically observed in-plant inspection personnel conducting zero-tolerance verification of establishment's procedures for controlling of feces or ingesta contamination and reviewed documented inspection verification results. The FSIS auditor and CCA did not observe any non-compliance related to zero tolerance deviation on the day of the audit. No concern arose because of FSIS audit observations and records review.

The FSIS auditor also reviewed and verified the application of CCA supervisory reviews at certified establishments. The reviews consist of the evaluation of the adequacy of establishments' food safety systems and delivery of official inspection and verification services. These reviews are conducted by the CCA's Senior Officer (SO) of the Control Department's Import, Export and Organic Control Unit Border Control Section in accordance with updated *EVIRA's Guidelines "Requirements for Export to the USA" 18511/1 (2014)* for inspection personnel and *18511/1 (2014)* for establishment operator. These documents contain instruction to inspection personnel; procedures regarding implementation including frequency of verification; documentation; and corrective actions for Sanitation, HACCP, *Salmonella* sampling, and *E. coli* sampling.

During this audit, FSIS verified that CCA's SO had documented outcomes of supervisory reviews, which are conducted six (6) times for slaughter processing establishments and two (2) times for cold storage facilities, per year. The supervisory reviews were conducted using a uniform detailed checklist. The supervisory reviews evaluate the adequacy of the establishments' food safety system and the capability of inspection personnel of conducting inspection activities at certified establishments.

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

The analysis and on-site verification activities showed that Finland's meat inspection system has the legal authority and a documented regulatory framework to implement EVIRA's regulatory

requirements, and that the CCA continues to maintain equivalence and is operating at an “average” level for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS’ program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOP.

FSIS reviewed the legislation, regulations, official instructions, and guidelines of the CCA and verified that the EVIRA uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Furthermore, FSIS verified that inspection personnel exercise their official authority as prescribed by the regulations of the system and follow guidance provided by *EVIRA’s Guidelines “Requirements for Export to the USA” 18511/1 (2014)* for inspection personnel and *18511/1 (2014)* for establishment operators to verify that the establishments adequately implement pre-requisite programs such as SSOPs, good manufacturing practices, and sanitation performance standards.

The CCA demonstrated that it enforces overarching EU sanitary regulations, including *EU regulations 852/2004 article 4 no 2 cf.; 4 no 3 and Annex II; 853/2004 article 3 cf. Annex II chapter I-VII, and Annex III; 854/2004 article 4(2)*, which have been determined to be equivalent to FSIS requirements. There are no fundamental differences between the United States and European Union sanitary risk control systems. In addition, Finland incorporated FSIS regulations in 9 CFR Part 416 into its export requirements for the United States. *Finnish Sanitation Guideline No. 662/32/03, EVIRA Guideline No. 18510/1* for the establishment personnel and *EVIRA Guideline No. 18511/1* for official veterinarians of the United States 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 18511/1*, 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 frequency of SSOP and SPS inspection verification tasks are risk-based. The frequency of sanitation procedures verification by inspection personnel is set as daily.

The FSIS auditor gathered audit evidence through direct observation of operations and review of the establishments’ associated records. The FSIS auditor observed in-plant inspection verification of operational sanitation procedures at the two establishments audited. The FSIS auditor verified whether pre-operational inspection at one of the establishment was adequate - by directly observing the in-plant inspection personnel conducting pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity in accordance with the established procedures, including a pre-operational record review of the results of the previous day’s establishment microbiological testing results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils, as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity).

The FSIS auditor observed in-plant inspection verification of operational sanitation procedures in all audited establishments and compared the overall sanitary conditions of all audited establishments to the CCA documentation. These verification activities included direct observation of operations and review of the establishment's associated records. The FSIS auditor's record review included sanitation monitoring and corrective action records over at least a 3-month period at all establishments audited, as well as those of the CCA documenting inspection verification results, non-compliance reports (*Epakohtaraportti*) and supervisory reviews of establishments. The auditor noted that, for the most part, the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. No concerns arose as the result of these document reviews.

However, FSIS identified SPS findings at both audited establishments concerning the CCA's ability to exercise regulatory control over facility maintenance, ventilation above exposed product areas, and maintenance of direct product contact equipment of establishments eligible to export to the United States. The FSIS auditor did not observe any direct product contamination.

Discussions with inspection personnel and CCA verification records and supervisory reviews indicated that some of the observed conditions related to the conveyor belts that are in direct contact with product had been previously identified by the CCA SO and inspection personnel. It was also documented that the establishment had ordered some conveyor belts for the processing line. While this is acceptable in the long term, inspection personnel should have required the establishment to take immediate action to address this situation as in some sections of the belts were in extensive state of deterioration.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS demonstrate that the Finland inspection system provides requirements equivalent to those of the United States system for sanitation performance standards, sanitary handling of products, and the development and implementation of SSOPs that prevent direct product contamination. However, the CCA must ensure that in-plant officials improve their ability to evaluate the sanitation programs implemented by the establishments to ensure that they remain in compliance with the regulations of the system. FSIS identified a need for the CCA to better assess the corrective actions proposed by establishments (immediate and preventive) certified for export to the United States in response to SPS non-compliances as they relate to the facility and equipment maintenance requirements.

FSIS requests that the CCA provide a detailed response for each of the identified findings within this component within 60 calendar days of receipt of this report. Furthermore, FSIS requests that the CCA verify and document the adequacy of implementation of the corrective measures proposed by the slaughter and processing establishments, and provide FSIS the results of the verification activities within its comments to this report.

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

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

The verification and evaluation of this component included *Finland's Law, EVIRA Guidelines for Establishment Personnel (18510/1)* and *Official Veterinarians (18511/1)* of United States-Eligible Establishments, adopted FSIS requirements cited in 9 CFR part 417, and General Instructions for Auditing HACCP Systems. These issuances require that establishments exporting to the United States develop, implement, and maintain HACCP programs that must be approved by the CCA. The auditing unit of EVIRA manages the HACCP program reviews and auditing activities. The design and implementation of all certified establishments' HACCP programs are reviewed yearly, prior to granting of export certification renewal.

The approval process includes the review of all aspects of the written HACCP programs, based on procedure 9 CFR Part 417 and *EVIRA's HACCP Guideline No. 10002/2*. The auditing unit within EVIRA reviews HACCP program documentation to verify that the design of the program meets regulatory requirements. It also verifies that establishments include in their written program the individuals who form the HACCP team; a description of products, including their shelf life; accurate flow charts describing processing steps and flow of product; hazard analyses for each step in the process; and the HACCP plans prepared to control identified hazards. The evaluation also assesses the design of critical control points (CCPs), their validation, and the scientific knowledge that supports the decisions made by the establishments to select the critical limits.

The FSIS auditor reviewed *EVIRA Guidelines No. 18511/1* 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 three months. The FSIS auditor's review indicated that the HACCP documents generated by establishment were in compliance with *EVIRA's HACCP Guideline No. 10002/2* and adopted FSIS requirements in 9 CFR Part 417.

FSIS verified that in-plant inspection personnel conducted daily verification of HACCP plans in accordance with aforementioned *Finnish Guideline No. 10002/2*. In-plant inspection personnel are responsible for performing verification activities that include the review of the establishment's written HACCP plans and their contents, review of establishment generated HACCP monitoring and verification records and direct observation of those procedures by the establishment to assess the adequacy of implementation of HACCP plans on the part of the establishments. Official veterinarians use a monthly assignment schedule that they develop that direct them to conduct specific HACCP program verification tasks and prepare daily reports of findings and actions taken. There was no indication of any non-compliance trends resulting from the review of these documents.

At the two swine slaughter processing establishments audited, the FSIS auditor conducted an on-site review of the zero tolerance (feces or ingesta contamination) CCP records generated during the past six months. In addition, the FSIS auditor reviewed the verification records associated with EVIRA zero tolerance inspection tasks. The review of these records indicated that one establishment identified a few deviations from the critical limit while inspection verification records showed no zero tolerance non-compliances for the same timeframe. The review of the establishment's corrective actions in response to the observed deviations from the zero tolerance critical limit indicated that all four parts of the corrective actions were adequately addressed in accordance with requirements consistent with 9 CFR 417.3, when deviations occurred and were verified by inspection personnel. Additionally, the FSIS auditor observed the inspection personnel conducting HACCP hands-on verification activities at this CCP location, making direct examination of swine carcasses. The inspection personnel and the FSIS auditor observed no deviation from the critical limits on the day of the audits.

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 conducting inspection task indicated an adequate HACCP food safety system in the audited establishments. The analysis and on-site verification activities indicated that the CCA is operating at an "average" level.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

FSIS based its verification of Finland's residue control program on information contained in *Council Directive 96/23/EC of 29 April 1996, Finland Law*, and Finland's Annual Residue Control Plan (2015), in association with the previous two year's (2013 and 2014) testing results. These documents indicate that EVIRA continues to maintain the legal authority to regulate, plan and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of swine slaughtered for processing into meat for human consumption. This regulatory task is accomplished with the participation of the National Residue Reference Laboratory - The Chemistry and Toxicology Research Unit, the Food and Feed Microbiology Research Unit, and the Risk Assessment Unit of the Research and Laboratory Department of EVIRA.

During the on-site audit, the FSIS auditor reviewed Finland's Chemical Residue Control Programs at the CCA's headquarters, two slaughter and processing 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 veterinarians to verify the proper implementation of the National Residue Program at each inspection level.

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. The procedures followed by the CCA when a positive or violative result occurs are to identify the animal and farm of origin, investigate the cause of the violation at the farm, safeguard the public health by product disposition, intensify the checks on the animals and products from the farm, and impose criminal or administrative penalties against any person who is responsible. Finland, as a member of the European Union, has residue plans that are acceptable by European Union standards and therefore recognized as equivalent to FSIS' criteria.

FSIS' review of Finland's National Residue Program indicated that Finland's national testing plan for 2014 was effectively implemented as designed, and the 2015 plan was on schedule. Inspection personnel within the slaughter facilities collect tissues of randomly selected slaughtered animals in accordance with the prescribed methodology provided by the Food Hygiene Unit of EVIRA. FSIS' review of documentation at the two local inspection offices audited indicated that in-plant officials were collecting samples of the required matrices for detection of specific analytes and adhering to the prescribed sample collection schedule. FSIS' review of the monitoring results for 2013, 2014, and 2015 to date indicated that no violative samples were detected. FSIS' review of POE import data has not identified any violations for chemical residues during routine testing of product from Finland that occurs at United States POE since the last audit in 2012.

The Chemistry and Toxicology Laboratory, which serves as the official laboratory conducting analysis of government samples for the presence of chemical residues in meat products, is 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 to ISO 17025, checked every year by FINAS, and re-audited every 4 years. It analyzes the majority of all NRCP samples and conducts all chemical analyses. 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.

During the audit of The Chemistry and Toxicology Laboratory, FSIS reviewed training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully participated in intra- and inter-laboratory evaluations administered by the laboratory manager and accrediting bodies. Furthermore, records and past internal laboratory audit reports demonstrate that laboratory managers readily respond to correct non-conformities identified during internal and external audits. Documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analysis within their accreditation scope.

In addition, the FSIS auditor observed and verified sample handling, sampling frequency, and verified the trace-back of a selected sample from a United States eligible establishment. The FSIS auditor verified that the laboratories do a timely analysis of samples, and that they timely report data to the CCA, apply approved analytical methodologies, use proper tissue matrices and intra-laboratory check samples, and have laboratory quality assurance programs including

standards books and corrective actions. No concerns arose because of these observations and reviews.

The meat inspection system of Finland has regulatory requirements that are necessary for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs, muscle, and fat of carcasses for chemical residues, and the program is adjusted on a yearly basis to address emerging concerns. The program also contains provisions that, in accordance with Finland Law, impose criminal or administrative penalties against any person who knowingly supply establishments with swine that exceed violative residue levels. The analysis and on-site verification activities indicate that the CCA is operating at an "average" level.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was government Microbiological Testing Programs. The system must be designed to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of *EU Regulation 2073/2005 of November 15, 2005, on Microbiological Criteria for Foodstuffs*, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. According to *EU Regulation 852/2004*, all establishments producing products for human consumption must implement and maintain a permanent procedure based on HACCP principles. Specific rules for testing and minimum sampling are written in *EU Regulation 2073/2005*. Finland has equivalence determinations in place that allows trained either establishment or government employees to take samples applicable to generic *E. coli* and *Salmonella* testing programs.

Finland has an establishment-conducted microbiological testing program for *Enterobacteriaceae* that requires implementation by all slaughter establishments to show process control. 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. Enterobacteriaceae testing has been accepted as equivalent to generic *E. coli* by FSIS. However, establishments that are certified eligible for export to the United States have the option of conducting generic *E. coli* testing instead. Finland has adopted the FSIS regulatory requirements for testing for generic *E. coli*, which are set out in 9 CFR 310.25, with the exception of the following equivalent measures: Finnish establishments use a gauze swab sampling tool and an accredited private microbiology laboratories use an AOAC approved NMKL method or AOAC Petrifilm method to analyze samples for generic *E. coli*. *E. coli* sampling is in accordance with adopted 9 CFR 310.25 for generic *E. coli* and *EU regulation 2073/2005* for *Enterobacteriaceae*.

Carcass sampling for generic *E. coli* is performed by the establishment personnel and sent to the accredited private laboratory. Inspection personnel verify that the establishment's written plan

addresses the location of sampling, randomness of sampling, and sample integrity; that establishment uses appropriate sampling methodology; that the lab uses an appropriate method for analysis; that the results are correctly evaluated; and that establishments take appropriate corrective action when a violation occurs.

The FSIS auditor verified through document reviews and direct observation that the two audited slaughter and processing certified establishments had implemented a generic *E. coli* testing program to verify process control of livestock carcasses in accordance with Finnish regulations. The 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 showed that the establishments routinely met their limits as determined by statistical process control. The FSIS auditor's review of the establishment's generic *E. coli* in-plant testing program and of establishment records did not reveal any non-compliance or concerns because of this review.

Finland's inspection system also 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 310.25 and *Finnish National Salmonella Regulation No. 20/EEO/2001*. The frequency of *Salmonella* sampling is set by the CCA, and the sample includes both carcasses and lymph nodes. FSIS applied the same verification methodology as was stated for generic *E. coli* and concluded that *Salmonella* sampling complied with aforementioned regulatory requirements.

The FSIS auditor reviewed Finland's *Salmonella* sampling and testing program, the implementation of the program within the certified establishment by the in-plant personnel, and the results and records resulting from the program. Sampling and testing of carcasses for *Salmonella* occur in all certified establishments that slaughter livestock. Carcass sampling for *Salmonella* species is performed by the establishment under the observation of the CCA. The CCA verifies that all certified establishment sample collection procedures are in accordance with its sample collection protocols described in *EVIRA's Guideline 18511/1* and *Finnish National Salmonella Regulation No. 20/EEO/2001*. The FSIS auditor's review of 120 days of records at the two slaughter and processing establishments audited identified that no *Salmonella* set failures had occurred.

The EVIRA inspection personnel routinely verify that the establishments follow all the requirements listed in *EVIRA's Guideline 18511/1*. The planning of the in-plant inspection verification is made in accordance with the CCA weekly inspection task plans outlined in Finnish document titled "*n vientiin hyväksytyjen laitosten viranomaisvalvonta.*" The CCA performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/pathogen reduction studies) to determine the ongoing effectiveness of the inspection system for *Salmonella* Performance Standards.

FSIS also audited the Atria Oyj Microbiological Laboratory, a private laboratory. The FSIS auditor verified that the laboratory was accredited under ISO 17025. This accreditation contains all microbiological analyses necessary to support the certified establishments. The FSIS auditor

reviewed training materials and records along with the results of proficiency testing. Proficiency testing is proceeding as designed, and all results reviewed were acceptable. 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 because of this visit.

In conclusion, the audit found that EVIRA continues to meet the core equivalence requirements for this component. Identified issues with the private microbiological laboratory's quality management system (ISO 17025) were previously addressed in the Government Oversight component. An assessment of the non-conformities previously identified in the Government Oversight component reaffirmed that, while the deficiencies do not represent an immediate risk to public health, they could ultimately affect the accuracy of test results.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component. However, FSIS requests that EVIRA describe changes made within the context of its quality management system to ensure the accuracy of future microbiological laboratory testing results, as previously addressed in the Government Oversight component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 17, 2015, in Helsinki with EVIRA. At this meeting, the FSIS auditor presented his preliminary findings. The CCA understood and accepted the findings.

The significant audit findings are as follows:

- The CCA was using non-government employees (establishment employees) to conduct post-mortem inspection examinations when short staffed. This is indicative of a serious conflict of interest between the CCA and the establishment at which it provides inspection.
- The CCA is not adequately assessing the corrective actions proposed by establishments (immediate and preventive) with respect to their SPS related to facility and equipment maintenance.

In response to FSIS audit findings presented at the audit exit brief, FSIS has received a letter from the Finnish Food Safety Authority (EVIRA) (Reference attached letter United States -audit 4.-3.17.2015 titled MAARAYS LIHANTARKASTAJIEN SIJAISISTA). The letter states that EVIRA has halted the practice of using establishment employees to conduct post-mortem inspection duties and will only use official inspection personnel to conduct all related inspection duties. Additionally, EVIRA issued a Notice of Intent to Delist (NOID) on March 16, 2015, to the two audited establishments, which are the only establishments certified to export to the United States, related to issues identified during the course of the audit. The FSIS auditor was informed that EVIRA would conduct a targeted follow-up audit to verify the implementation of

corrective actions taken by the establishments. EVIRA promised to address the audit findings with inspection personnel during a training session in May 2015.

FSIS requests that the CCA provide a detailed response for each of the identified findings within 60 calendar days of receipt of this report. The CCA's initial response during the audit was satisfactory. Specifically, FSIS requests further information and evidence of corrective actions from Finland as to how they plan to provide inspection coverage when a staffing shortage occurs at establishments long-term, as well as, the results of its follow-up audit and training session.

ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: Foreign Country Response to Draft Final Audit Report (when available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Ruokatalo Oy Teollisuuskatu 17 Forssa 30420	2. AUDIT DATE 03/12/2015	3. ESTABLISHMENT NO. 18	4. NAME OF COUNTRY Finland
	5. NAME OF AUDITOR(S) Kenneth B. Witek - SPA, CSO		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment HK Ruokatalo Oy - Forssa 30420, Est. 18, Pork Slaughter & Processing, 03/12/2015

39/51 Various deficiencies in the maintenance of overhead structures were observed by the FSIS auditor in the
 56 establishments Fabrication Department. Observations included rust developing on air exchange units, rail switch, pipe valve and some equipment fasteners thereby creating insanitary conditions which could result in the contamination of product (although no direct product contamination observed).
 [Regulatory reference: 9 CFR 416.2(b), 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

45/51 During the FSIS' auditor's observation of pre-operational sanitation verification by Evira various deficiencies in the
 56 maintenance of equipment that comes in contact with exposed product were observed by the FSIS auditor in the Fabrication Department. Observations included:
 1. Several vinyl conveyor belts that carry exposed product were in a deteriorated condition
 2. Several white fiber product tubs (cracks) and boning cutting boards (deep scores)
 3. Numerous S/S bins that carry exposed product with cracks and metal edges pulled apart

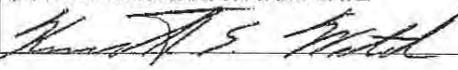
Immediate corrective actions were taken by the establishment and verified by Evira with additional measure to prevent the reoccurrence be provide to inspection personnel.
 [Regulatory reference: 9 CFR 416.3, 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

Note: Evira stated that the establishment has initiated a plan of action to address these issues and reassess their maintenance of equipment and facility programs.

49 FSIS Auditor's interview of Supervisory Official Veterinarian (SOV): It was stated that when short term relief inspection is needed and there is no auxiliaries (inspectors) available that the SOV can request the temporary employment of establishment employees to conduct post-mortem inspection of the heads and viscera when there is no available alternative. The auditor's review of inspection staffing record at the establishment identified on several occasions each month employees of the establishment being hired to fill inspection personnel slots that conduct post-mortem inspection duties on a day-by-day bases.

Finland's previous submitted documentation through the SRT identifies that Evira assigns the inspection personnel to the U.S.-eligible establishments (warrant of appointments of the inspection personnel). The inspection personnel assigned to establishments certified to export to the United States are to be employees of the national government. This practice of using establishment employees to conduct post-mortem inspection leads to a direct conflict of interest between the CCA (Evira) and the establishment for which they provide regulatory oversight on.
 [Regulatory reference: EEC Regulation 854/2004; Food Act 23/2006: Chapter 8 – Section 30 – Central Competent Authority, the National Food Agency (part of Evira); Monitoring Plan Statute (665/2006)]

61. NAME OF AUDITOR
 Kenneth E. Witek – SPA, CSO

62. AUDITOR SIGNATURE AND DATE
 3/12/15

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Atria Oyj PL 900 Nurmo 60550	2. AUDIT DATE 03/9-10/2015	3. ESTABLISHMENT NO. 22	4. NAME OF COUNTRY Finland
	5. NAME OF AUDITOR(S) Kenneth E. Witek - SPA, CSO		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment Atria Oyj - PL 900, Nurmo, 60550: Est. 22, Pork Slaughter & Processing (03/9 & 10/2015)

Pre-Operational Observations:

41/51 During the FSIS' auditor's observation of pre-operational sanitation verification by Evira the auditor observed frozen condensate on a freon line unit over exposed product conveyor line in the Fabrication Department. There was not measure to safe guard the freon line unit from the possibility of dripping on to the product when in production (e.g. catch tray/pan underneath the unit), thereby creating a insanitary condition which could result in the contamination of product.

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

[Regulatory reference: 9 CFR 416.2, 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

45/51 During the FSIS' auditor's observation of pre-operational sanitation verification by Evira various deficiencies in the maintenance of equipment that comes in contact with exposed product were observed by the FSIS auditor in the Fabrication Department. Observations included:

56

1. Numerous vinyl conveyor belts that carry exposed product were in a deteriorated condition
2. Several white fiber product tubs (cracks) and boning cutting boards (deep scores)
3. Several S/S bins that carry exposed product with cracks and metal edges pulled apart

The review of Internal Audit (periodic supervisory review) reports conducted by Import, export and Organic Control Unit and inspection verification records demonstrated documentation of some conveyor belt deficiencies and that the establishments were waiting for belts to arrive. However inspection personnel should have required the establishment to take immediate action to address this situation.

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

[Regulatory reference: 9 CFR 416.3, 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

Note: Evira stated that the establishment has initiated a plan of action to address these issues and reassess their maintenance of equipment and facility programs.

49 FSIS Auditor's interview of Supervisory Official Veterinarian (SOV): It was stated that when short term relief inspection is needed and there is no auxiliaries (inspectors) available that the SOV can request the temporary employment of establishment employees to conduct post-mortem inspection of the heads and viscera when there is no available alternative. The auditor's review of inspection staffing record at the establishment identified on several occasions each month employees of the establishment being hired to fill inspection personnel slots that conduct post-mortem inspection duties on a day-by-day bases.

Finland's previous submitted documentation through the SRT identifies that Evira assigns the inspection personnel to the U.S.-eligible establishments (warrant of appointments of the inspection personnel). The inspection personnel assigned to establishments certified to export to the United States are to be employees of the national government. This practice of using establishment employees to conduct post-mortem inspection leads to a direct conflict of interest between the CCA (Evira) and the establishment for which they provide regulatory oversight on.

[Regulatory reference: EEC Regulation 854/2004; Food Act 23/2006: Chapter 8 – Section 30 – Central Competent Authority, the National Food Agency (part of Evira); Monitoring Plan Statute (665/2006)]

61. NAME OF AUDITOR

Kenneth E. Witek – SPA, CSO

62. AUDITOR SIGNATURE AND DATE

Kenneth E. Witek

3/10/15

ANSWER TO FSIS
DRAFT FINAL RE-
PORT OF AN AUDIT
CONDUCTED IN FIN-
LAND MARCH 4-17,
2015

Control Department
Import, Export and Organic Control Unit

Pvm/Datum/Date
02.07.2015

Dnro/Dnr/DNo
668/0477/2015

Shaukat H. Syed
Director

International Audit Staff
Food Safety and Inspection Service
Office of Investigation, Enforcement and Audit
1400 Independence Avenue, SW
Washington, D.C.
USA

Director Shaukat H. Syed,

The Finnish Food Safety Authority Evira understands the findings reported in the Food Safety and Inspection Service (FSIS) draft final report concerning the on-site equivalence verification audit conducted in Finland by FSIS from March 4-17, 2015. During the closing meeting of the audit Evira informed the FSIS auditor about the immediate corrective actions Evira has taken and the action plan set to follow up the detected non-compliances. FSIS asked on March 26, 2015 to send FSIS information regarding staffing, results of follow-up audits and information about the training session in May 2015. Evira replied on April 22, 2015 to that request. With the present letter Evira gives some additional information on those issues and replies also to topics present in the draft final report but not considered by FSIS as significant findings.

Use of non-government employees when short staffed

As response to staffing shortage Evira has recruited more official auxiliaries. Evira's Import, Export and Organic Control Unit which is responsible for the equivalence and operates the export control system in place for export of pig meat to USA has also performed an internal audit on Evira's Meat Inspection Unit which is responsible for inspection personnel in slaughterhouses and connected plants on June 29, 2015, focusing on the written contracts of the employment between Evira and the substitutes of auxiliaries. In addition the chief official veterinarians working in Atria Nurmo and HKScan Finland Forssa have been asked to present additional guarantees that there has not been any establishment employees working as

Control Department
Import, Export and Organic Control Unit

Pvm/Datum/Date
02.07.2015

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auxiliaries after March 17, 2015, when Evira has halted the practice of using establishment employees to conduct post-mortem inspection duties. The guarantees have been presented and found satisfactory.

Assessment of corrective actions with respect to SPS

According to the draft final report Evira is not adequately assessing the corrective actions proposed by establishments with respect to their SPS related to facility and equipment maintenance. In order to address the corrective actions the CCA's Senior Officer operating the export control system in place for export of pig meat to USA has increased the frequency of SPS audits in the audit plan focusing on conveyor belts, rust, ventilation and condensation as response to findings concerning sanitation standards (SPS) related to maintenance. Frequency has been increased by two additional SPS checks to Evira's audit plan concerning establishments exporting pig meat to USA in 2015. In addition the chief official veterinarians of both establishments (establishments number 18 and 22) have increased the inspections of those topics and added these changes to their control plans. Also establishments have increased the frequency of own checks related to those topics in their own check plans. The SPS findings detected by FSIS have been seriously considered and corrective actions have taken place. The establishments, official veterinarians and Evira all have increased the control actions related to SPS findings to correct any deviations and prevent them to further occur.

In addition, in the end of 2015 Evira will evaluate the results of the corrective actions taken, the preventive measures taken and the results of the additional audits concerning SPS Evira is going to perform until the end of this year and will assess the need to modify its guidelines and/or the proposed frequency of inspections and audits.

Training

In order to correct a misunderstanding Evira would like to clarify that the training session in May 2015 (6.-7.5.2015) was held by the HACCP Consulting Group, not Evira. The program of the training is enclosed to this letter. One of the subjects was "Current FSIS Sanitation Standard Operating Procedures (SSOP) – How to sanitize". Some of the audit findings were covered in that training session in addition to other issues as presented in the training program. The rest of the findings presented in the draft final report will be covered in Evira's own annual USA export training session which is planned to be held on September 29, 2015.

Control Department
Import, Export and Organic Control UnitPvm/Datum/Date
02.07.2015Dnro/Dnr/DNo
668/0477/2015**Laboratory findings**

As response to two findings related to the private microbiological laboratory of Atria Nurmo the corrective actions have been initiated and are planned to be completed by the end of September 2015. The laboratory has ordered a continuous working temperature monitoring system called Sensire apparatus. Continuous working temperature monitoring system will be installed and harnessed by September 30, 2015. In addition official veterinarians of Atria Nurmo will follow up the installation of the system and perform a supervisory inspection by October 9, 2015 to ensure that corrective action has taken place according to the action plan. The other laboratory finding concerning the instability of the calibration, has already been corrected in implementation, in forms and in working instructions. The official veterinarians working in Atria Nurmo have followed up this issue.

Deputy Head of Unit
Import, Export and Organic Control Unit
Beata MeinanderDVM, Senior Officer
Import, Export and Organic Control Unit
Marianne Peltomaa



Robert Savage
4022 Nicholas Court
Fairfax, VA 22033
703)385-1989
savager3@verizon.net

ADVANCED HACCP TRAINING

May 6 - 7

AGENDA*

DAY ONE

- | | |
|------------|--|
| 8:30 a.m. | Registration/Coffee |
| 9:00: a.m. | Welcoming Remarks and Workshop Objectives |
| 9:15 a.m. | Overview of the FSIS Equivalence Process |
| 10:15 a.m. | Break |
| 10:30 a.m. | Current FSIS Sanitation Standard Operating Procedures (SSOP) – How to Sanitize |
| 11:30 a.m. | FSIS Food Safety Assessments (FSAs) |
| 12:15 p.m. | Lunch |
| 1:15 p.m. | HACCP Plan Hazard Analysis |
| 2:00 p.m. | Risk Assessment - Codex |
| 3:00 p.m. | Break |
| 3:15 p.m. | Microbiological Risk Assessment |
| | Chemical Risk Assessment |
| 5:30 p.m. | Adjourn |

Excellence In Food Safety Management





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ADVANCED HACCP TRAINING

DAY TWO

8:30 a.m.	Food and Drug Administration – iRisk
10:00 a.m.	Break
10:15 a.m.	Principles of Process Validation and Validation of Your HACCP plans
11:00 a.m.	Codex Validation Principles
12:15 p.m.	Lunch
1:15 p.m.	FSIS Validation Guidelines Validation of a Pork Slaughter Process
3:00 p.m.	Break
3:15 p.m.	FSIS Import Inspection Procedures
4:15 p.m.	FSIS Audit Findings Questions and Answers
5:15 p.m.	Adjourn

* Agenda may be modified based on current events

Excellence In Food Safety Management



ANSWER TO FSIS
INFORMATION RE-
QUESTControl Department
Import, Export and Organic Control UnitPvm/Datum/Date
22.04.2015Dnro/Dnr/DNo
668/0477/2015Shaukat H. Syed
DirectorInternational Audit Staff
Food Safety and Inspection Service
Office of Investigation, Enforcement and Audit
1400 Independence Avenue, SW
Washington, D.C.
USA**Dear Director Shaukat H. Syed,**

Enclosed to this letter are the audit reports from an audit FSIS conducted to Finland's meat inspection system March 4 -17, 2015. Enclosed to this letter are also the audit and inspection reports from the NOID audits (7.4.2015 and 9.4.2015) and the answers and corrective actions of the establishments 22 and 18. Establishments have also made changes to their control and own control so that these deficiencies would not occur again. Establishments have for example made program for belt changing. Also the scuff marks of the mixer have been investigated and the report of this investigation is enclosed to this letter.

As response to staffing shortage Finnish Food Safety Authority Evira is recruiting four more auxiliaries to the establishment 22 (Atria Nurmo) to substitute other auxiliaries. Two auxiliaries have already been recruited and two are recruited at the moment. Enclosed to this letter are also written contracts of the employment between Evira and the substitutes of auxiliaries from 17.3.2015.

Please note that the training session in May 2015 (6.-7.5.2015) is held by the HACCP consulting group, not Evira. The program of the training is enclosed to this letter. Some of the audit findings are handled in that training session and rest of the findings will be handled in Evira's own annual USA export training session which will be arranged 29.9.2015.

Head of the Unit

Senior Officer, DVM


Tiina Lapveteläinen
Marianne Peltomaa

Control Department
Import, Export and Organic Control Unit

Pvm/Datum/Date
22.04.2015

Dnro/Dnr/DNo
668/0477/2015

Annexes

I: Audit and Inspection reports from USDA audit 9.-11.3.2015 Atria Ltd Nurmo (establishment 22)

II: Audit and Inspection reports from USDA audit 12.3.2015 HKScan Finland Ltd Forssa (establishment 18)

III: Reply to NOID (Establishment 22 Atria Ltd Nurmo)

IV: Reply to NOID (Establishment 18 HKScan Finland Ltd Forssa)

V: Audit and Inspection reports from NOID audit 7.4.2015 and Atria's report from scuff marks of the mixer (Atria Ltd Nurmo, Establishment 22)

VI: Audit and Inspection reports from NOID audit 9.4.2015 (HKScan Finland Ltd, Establishment 18)

VII: Program of the training session held by the HACCP consulting group

VIII: Written contracts of the employment between Evira and the substitutes of the auxiliaries from 17.3.2015.

Evira
 IMPORT, EXPORT AND ORGANIC CONTROL (RALU)
 Import and Export Department

Date	Reg. no.	Page(s)
31.03.2015	76/0477/2015	1 (1)

Senior Inspection Veterinarian
 Irmeli Sippola
 Atria Oyj
 P.O. Box 117
 60101 SEINÄJOKI, FINLAND

AUDIT REPORT

For your consideration and future procedures, The Finnish Food Safety Authority dispatches the following annexed audit report, written for the audit of the supervisor of the facility approved for U.S. exports at the Atria Oyj's facility no. 22 in Nurmo, Finland on the 9th – 11th of March 2015.

Head of Unit Import, export and organic control	Tiina Lapveteläinen
--	---------------------

Senior Inspector Import, export and organic control	Marianne Peltomaa
--	-------------------

Annex Audit report Reg. no. 76/0477/2015

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IMPORT, EXPORT AND ORGANIC CONTROL
Mustialankatu 3, 00790 HELSINKI, FINLAND
Tel. +35829530 0400 Fax +35829530 4354

Date 31.03.2015 Reg. no. 76/0477/2015

Audit of supervisor of facility approved for U.S. exports

Name of facility: Atria Oy, Nurmo, Finland

Facility approval number: 22

Supervising authority: Governmental inspection veterinarian

Audit date: 9. – 11.3.2015 (9. – 10.3.2015 for facility and 11.3.2015 for laboratory)

Auditor: Senior Inspector Marianne Peltomaa

Present at audit: USDA auditor Kenneth E. Witek
Senior Inspection Veterinarian Irmeli Sippola
Inspection Veterinarian Marja Fossi
Senior Inspector Tua Goldman
Director Markku Hirvijärvi
Director Tauno Perälä
Production Manager Tuomas Viita
Slaughterhouse Manager Sami Roiha
Slaughterhouse Foreman Marko Talso
Cutting plant Foreman Ville Valli
Quality Director Seija Pihlajaviita
Quality Manager Katja Lehtinen
Laboratory Foreman Hannu Kangasmaa
Laboratory Quality Correspondent Riitta Ojaniemi

Signature:

General

The audit in question was carried out in conjunction with the U.S. Department of Agriculture's (USDA) inspection. The inspection was carried out by Kenneth E. Witek.

1. AUDIT PLAN

Topics for audit plan

The Finnish Food Safety Authority's (Evira) audit plan topics for the month were:

1. the slaughterhouses and cutting plant's SPS/SOP program for codes of standard and non-standard conduct
2. the cutting plant's HACCP program
3. the cutting plant's HACCP program's records
4. records of animal welfare inspections
5. pre-production cleanliness inspections in the cutting plant
6. functionality of the cutting house's incoming inspection / its supervision
7. inspection of the animal transport vehicle
8. carrying out animal welfare inspections
9. supervision of SSOP program implementation in the cutting house during production
10. inspection veterinarians' zero-tolerance inspection at the slaughterhouse
11. inspection veterinarians' supervision plan for the year 2015
12. inspection veterinarians' animal transport vehicle's hygiene inspection records
13. inspection veterinarians' ante mortem records
14. inspection veterinarians' other supervision records and plans for the requested parts

Audit plan follow-up topics

There were no follow-up topics in Evira's audit plan.

Audit plan additional topics

Evira's audit plan included the following additional topics requested by USDA FSIS auditor Kenneth E. Witek:

1. the slaughterhouses HACCP program
2. the slaughterhouses HACCP program records
3. the slaughterhouses and cutting plant's SSOP program and records
4. salmonella supervision program
5. salmonella supervision program records
6. salmonella sampling procedure
7. E. coli sampling program
8. E. coli sampling program records

9. E. coli sampling procedure
10. foreign matter supervision program
11. foreign matter supervision program records
12. the laboratory's operation
13. supervision of SPS/SOP program implementation in the slaughterhouse and cutting plant during production
14. supervision of SSOP program implementation in the slaughterhouse during production
15. appropriateness of the slaughterhouses CCP tracking
16. verification of the laboratory's accreditation certificate
17. inspection veterinarians' and meat inspectors' education information and management of temporary workers
18. grievance reports by inspection veterinarians
19. supervision of meat inspectors' post mortem inspections by inspection veterinarians

2. SUPERVISION PLAN

Supervision plan topics

The topics of the inspection veterinarians' supervision plan for the day were the same as the topics of the audit plan in terms of the inspected topics.

Supervision plan follow-up topics

There were no follow-up topics in the inspection veterinarians' supervision plan.

Supervision plan additional topics

The additional topics in the inspection veterinarians' supervision plan were the same as in the audit plan.

3. OBSERVATIONS MADE DURING AUDIT

Inspection veterinarians' supervision plan

Of the inspection veterinarians' supervision plan, weekly supervision plans were audited.

Inspection veterinarians' supervision records

Of the inspection veterinarians' supervision records, weekly supervision records were audited.

Of the inspection veterinarians' supervision records, grievance report records were audited.

Of the inspection veterinarians' supervision records, ante mortem records were audited.

Of the inspection veterinarians' supervision records, the educational information of inspection veterinarians and meat inspectors as well as temporary worker management were audited.

Activities of inspection veterinarians

The inspection veterinarian carried out a zero-tolerance inspection of manure deposits at the slaughterhouses final inspection point.

The inspection veterinarian inspected how the meat inspectors performed a post mortem inspection. The performance of the meat inspectors was proper at all inspection points. The inspection veterinarian had no remarks concerning the performance of meat inspection.

4. ACTIVITIES OF INSPECTION VETERINARIANS: INSPECTING THE FUNCTIONING AND RECORDS OF THE FACILITY'S SELF-MONITORING PROGRAMS

Self-monitoring programs

FSIS auditor Kenneth E. Witek (hereafter the auditor) requested that the facility's representative demonstrate the SSOP and SPS/SOP program of the slaughterhouse and cutting plant. The facility's representative demonstrated the program. The program had been last updated 19.2.2015. The auditor had no remarks concerning the program.

The auditor requested that the facility's representative demonstrate the slaughterhouses HACCP program. The facility's representative demonstrated the program. The slaughterhouses HACCP program had been last updated 26.2.2015 and the flowchart was last verified 28.4.2015. The monitoring, verification and re-inspection instructions of the slaughterhouses HACCP program were inspected. Special attention was also paid to the randomness of tracking periods and to program-specific corrective measures. The auditor had no remarks concerning the program.

The auditor requested that the facility's representative demonstrate the cutting plant's HACCP program. The facility's representative demonstrated the program to the extent of gauge calibration and the carcass temperature tracking program. The auditor had no remarks concerning the program.

The auditor requested that the facility's representative demonstrate the salmonella supervision program. The facility's representative demonstrated the program. The salmonella supervision program had been updated 25.1.2014. The research method of salmonella samples (NMKL 71:99, swab samples), instructions for additional samples due to positive samples, sample amounts available from Evira and randomisation were clarified. **The auditor found the salmonella supervision program to meet requirements.**

The auditor requested that the facility's representative demonstrate the E. coli sampling program. The facility's representative demonstrated the program. The program had been updated 19.2.2015. The research method of E. coli samples (NMKL 147/93 and Evira guideline 3548/2) were demonstrated, and

according to the program the sampling frequency is at least 1 sample per 5000 carcasses, so that samples are collected and researched randomly from carcasses that have been frozen for at least 12 hours, usually 3 samples per week. The calculation methods for limit values and procedure limits were clarified. The E. coli sampling program was found to meet requirements.

The auditor requested that the facility's representative demonstrate the foreign matter supervision program to the extent of the antibiotic sampling program, research method and antibiotic research results. The foreign matter supervision program was found to meet requirements.

Records of self-monitoring programs

The auditor requested that the facility's representative present the slaughterhouses HACCP program records for the last 90 days. The facility's representative presented records for the period 1.12.2014 – 6.3.2015. The preshipment season summary records were also clarified. The auditor had no remarks concerning the slaughterhouses HACCP program records.

The auditor requested that the facility's representative present the cutting plant's HACCP program records from 90 days back. The facility's representative presented records for the period 1.12.2014 – 6.3.2015. The auditor had no remarks concerning the records.

The auditor requested that the facility's representative present the salmonella supervision program's records. The facility's representative clarified records for the years 2013 – 2015. In the pigs there had been no positive lymph node or swab results in that period. The auditor had no remarks concerning the salmonella supervision program's records.

The auditor requested that the facility's representative present the records for the E. coli sampling program results. In 2014, 4 samples out of 164 presented samples had exceeded the limit value. The auditor had no remarks concerning the E. coli sampling program result records.

The auditor requested that the facility's representative present the records for the foreign matter supervision program to the extent of antibiotic research results. In 2014, a suspicious result had been obtained four times in the antibiotic research, but all resamples had turned out to be negative. The auditor had no remarks concerning the foreign matter supervision program result records.

The auditor requested that the facility's representative present the records for animal welfare inspections. The facility's representative presented animal welfare inspection records to the extent of welfare inspections recorded in the piggery. The auditor had no remarks concerning the welfare inspection records.

Implementation of self-monitoring programs

The auditor inspected the way the facility implemented and supervised the pre-production cleanliness inspection of the cutting plant. There were many worn and frayed conveyor belts in the cutting plant. Some frayed edges were immediately cut off and new conveyor belts were ordered to replace worn ones. Some badly worn conveyors were banned from use until new belts can be installed. In addition, a scraper support in one of the blenders had ground marks on the inside of the blender, possibly loosening pieces of metal into the produce. These faults resulted in Evira issuing the facility a warning of

revoking their export approval in conjunction with the audit (NOID). Other grievances observed during the audit are listed in more detail in the inspection veterinarian's inspection report.

The auditor inspected the way the facility implemented and supervised the SSOP program's and SPS/SOP instructions' implementation supervision in the slaughterhouse and cutting plant during production. Several SSOP and SPS/SOP grievances were observed in the slaughterhouse, cutting plant and carcass shipment facility. The grievances are presented in more detail in the inspection veterinarian's grievance report. The facility's representatives immediately fixed the faults detected at SSOP locations and the faults in SPS/SOP locations were either fixed immediately or recorded as requiring fixing. No remarks were made concerning the facility's representative's inspection, observations or corrective procedures.

The auditor inspected the way the facility's representative carried out the slaughterhouses CCP tracking. The facility's representative inspected the cleanliness of 10 carcasses in the post-inspection area. The tracking and records made by the facility's representative were, according to the self-monitoring program. The auditor had no remarks concerning the facility's representative's inspection, observations or corrective procedures.

The auditor observed the facility's representative collecting a salmonella swab sample. The sample was collected according to regulations. The auditor had no remarks concerning the collection of the salmonella swab sample.

The auditor observed the facility's representatives collecting an E. coli sample. The sample was collected according to regulations. The auditor had no remarks concerning the collection of the E. coli sample.

The auditor observed the carrying out of an animal welfare inspection. First the unloading of a load of pigs was observed into the slaughterhouse piggery. Unloading the pigs took place in a calm and proper manner and the pigs were moving well. The pig feeding program and implementation was clarified for the auditor and ante mortem inspection records were presented. The separation instructions of dead and euthanised animals and preventing them from ending up for consumption were clarified for the auditor, as were the procedures for cutting the carcasses open and Evisa's special permit pertaining to animal colouring requirements. Stunning the pigs and tracking gas content were inspected. Herding in to the Butina stunning system was observed and the use of the backup stunning system was clarified. Equipment for securing the sting was also presented and tracking of the stunning results was demonstrated. The auditor had no remarks concerning the performance of the animal welfare inspection.

The auditor inspected the laboratory's functions. The facility's representative presented the auditor with the requested FINAS accreditation certificate. The laboratory's accreditation certificate is valid until 1.12.2016. The facility's representative demonstrated to the auditor the laboratory personnel's education registry, deviation corrections and notification dispatch times. Sampling and pretreatment instructions, salmonella instructions according to U.S. export requirements as well as audit and accreditation seasons were also reviewed. The correspondence of salmonella and E. coli results were compared with supervision results. No salmonella findings have occurred in swab samples in the years 2013 – 2015. In terms of E. coli results, the deviation reports for exceeded values in the year 2014 were reviewed. Reporting of findings was also reviewed. In the salmonella laboratory the auditor observed the entire sample handling process, including instruction and form inspections. In the laboratory the auditor remarked on the two following issues: 1) the refrigerators and incubators did not have

continuous temperature follow-ups, so their temperatures during e.g. weekends are not known. The facility's representatives informed the auditor that a system is planned for installation in the refrigerators and incubators that measures the temperature at all times and displays it on the laboratory computer. 2) The other remark concerned the laboratory's refrigerators' minimum and maximum temperature limits. The facility had not taken into account the temperature calibration uncertainty in the minimum and maximum temperatures as a result of which the facility actually allows temperatures below and above the minimum and maximum temperatures. The facility's representatives promised to make changes to the allowed temperatures, taking into account the temperature calibration uncertainty.

5. AUDIT ASSESSMENT

The weekly supervision plan and records presented by the inspection veterinarian were in accordance with Evira's guideline (18511/1). The auditor also did not have any remarks concerning them.

The inspection veterinarians have written grievance reports in accordance with Evira's guideline (18511/1) and no need for any remarks was observed. The auditor also did not have any remarks concerning them.

The ante mortem records presented by the inspection veterinarian did not need to be remarked on. The auditor also did not have any remarks concerning the records.

The inspection veterinarian's performance in inspection situations as well as the inspection veterinarian's questions and remarks to the facility's representatives were determined to be appropriate.

The inspection veterinarian's inspection report was written properly and was in accordance with Evira's inspection report guidelines (18511/1).

6. FOLLOW-UP TOPICS FOR THE NEXT AUDIT

The audit did not discover any grievances in the inspection veterinarian's performance that would need to be followed up.

The next audit (NOID audit) audits how the facility has corrected the grievances discovered by the USDA auditor and how the inspection veterinarians have tracked them. The correction of major grievances will be audited by a NOID audit within 30 days of the USDA audit.

The audit plan topics that were not audited this time will be postponed to the May audit.

7. THE FACILITY'S CONFORMITY WITH REQUIREMENTS AND FULFILLING EXPORT CONDITIONS

During the audit, the auditor discovered several conveyor belts in poor condition. These should have been noticed in self-monitoring and supervision and changed months ago. The facility had received several notifications about conveyor belts in poor condition also during Evira's previous pre-production cutting plant audit. Thus, the poor condition of the conveyor belts was considered a recurring food safety hazard. The scraper support of one of the blenders which had scraped marks on the blender wall may have loosened pieces of metal into the produce and thus also caused a food safety hazard. Due to these grievances the Finnish Food Safety Authority in conjunction with the audit issued the facility with a warning about revoking the export approval (NOID). Other grievances noticed during the audit are listed in more detail in the inspection veterinarian's inspection report.

Evira
Control Department

INSPECTION REPORT

Date 20.3.2015

Reg. no.
76/0477/2015

Inspection report of facility approved for U.S. exports

Name of facility Atria Oy, Nurmo, Finland	Approval number of facilities 22
Supervising authority Evira	
Inspector Inspection Veterinarian Irmeli Sippola; USDA auditor Kenneth Witek	
Inspection date 9. – 11.3.2015	

Present at inspection

Senior Inspector Marianne Peltomaa,
Senior Inspector Tua Goldman,
Director Markku Hirvijärvi,
Director Tauno Perälä,
Production Manager Tuomas Viita,
Slaughterhouse Manager Sami Roiha,
Slaughterhouse Foreman Marko Talso,
Cutting plant Foreman Ville Valli,
Quality Director Seija Pihlajaviita,
Quality Manager Katja Lehtinen,
Laboratory Foreman Hannu Kangasmaa,
Laboratory Quality Correspondent Riitta Ojaniemi

To be notified

Finnish Food Safety Authority;
A-Sikateurastamo Oy:
Markku Hirvijärvi, Tuomas Viita, Sami Roiha,
Jari Palomäki, Marko Talso,
Rainer Roukala, Ville Valli,
Seija Pihlajaviita, Katja Lehtinen, Tiina Myllyllä, Pigvet

Inspector's signature

Evira

Inspection topics

1.

1. Supervision plan topics:

- SSOP program for slaughterhouse and cutting plant
- Standard and non-standard codes of conduct for the slaughterhouses and cutting plant's SPS/SOP program
- The cutting plant's HACCP program and records
- Preproduction cleanliness inspection (SSOP/SOP) in the cutting house
- Inspections during SSOP/SOP production in the cutting plant, carcass shipment facility and slaughterhouse
- Animal welfare program, implementation and records

2. Supervision plan follow-up topics: no follow-up topics

3. Supervision additional topics:

- The slaughterhouses HACCP program and records
- The slaughterhouses HACCP program tracking
- Salmonella supervision program and records
- E. coli sampling program and records
- Foreign matter supervision program and records
- The laboratory's functions

4. Audit plan follow-up topics: no follow-up topics

5. Audit plan additional topics: the same as in the supervision plan

Observations made during the inspection

2.

The slaughterhouses and cutting plant's SSOP program and SPS/SOP programs' codes of standard and non-standard conduct

Seija Pihlajaviita presented the SSOP/SOP program, updated 19.2.2015, and its associated tracking programs implemented before and during production in both shifts. She described the programs for SAQ/TAL (in HACCP working groups) and their 4 times a year implemented evaluations and yearly re-evaluations.

The division of hygienic areas, the washing programs for different areas and power washing were clarified. Deviation report practices for SSOP grievances determined and corrected before production have been instructed in detail.

The auditor raised the question about when an SOP observation becomes a product safety risk, because in production hygiene tracking the evaluator records an assessment of each observation and its potential product safety risk. According to the facility's clarification, a fault repeated by the same person can cause a risk.

The program was determined to meet the U.S. requirements.

The slaughterhouses HACCP program and records

Marko Talso presented the slaughterhouses HACCP program, updated 26.2.15, and its records for at least 90 days, 1.12.14 – 6.3.15. Kenneth Witek inspected the monitoring, verification and re-inspection instructions and paid special attention to the randomness of tracking periods as well as to corrective program-specific procedures. He stated that the program-specific re-inspection is at 100% and that the program describes additional monitoring for both tracking and verification. The performance inspections described as corrective procedures were also reviewed. The flowchart had been last verified 28.4.14. The previous re-inspection date was retrieved from the HACCP records as it did not occur in the inspected 90 day period. Re-inspection was recorded for 3.10.14. At inspection points 1 and 2 the activities were verified and corrective procedures were recorded in a facility deviation report.

The preshipment season's summary record entries for each U.S. export shipment were clarified, and additionally month-by-month.

Seija Pihlajaviita clarified briefly the microbiological sampling systems used to support HACCP.

HACCP and its records were determined to comply with requirements.

The cutting plant's HACCP program and records

The HACCP program, updated 26.2.15, was inspected to the extent of gauge calibration and the carcass temperature tracking program. Records were checked for the period 1.12.14 – 6.3.15.

The program and records were determined to comply with requirements.

Separation instruction

Instruction 30.7.14 was reviewed briefly by stating that the cutting plant only handles carcasses slaughtered at facility 22.

Salmonella controls and records

Seija Pihlajaviita presented the salmonella control program, updated 25.1.14. The research method for swab samples has been NMKL 71:99 as per program. Instructions for collecting additional samples due to positive samples were clarified.

The sample amounts, randomisation and sample results of the salmonella program provided by Evira were reviewed for the years 2013 – 2015. Hannu Kangasmaa clarified the sample results. In the pigs no positive lymph node or swab sample results were obtained during this period.

The salmonella control program was determined to comply with requirements.

E. coli sampling and records

Hannu Kangasmaa presented the E. coli program, updated 19.2.15. As per the program, the sampling has been randomised so that 3 E. coli samples are investigated per week, collected from random carcasses frozen for at least 12 hours. The method is NMKL 147/93 and Evira's guideline 3548/2. Sampling frequency is at least 1 sample per 5000 carcasses.

The procedure limit and method for calculating limit values was reviewed 11.3.15 in conjunction with inspecting the laboratory. The procedure limit is set at the previous year's sample result standard deviation X 3. The limit value for a good result is the average of the previous year's results. The limit

values vary from one year to another. 4 out of 164 samples exceeded the limit value in 2014. Their deviation reports were inspected and deviation correction measures were discussed. In 2015, 28 samples had been collected by 9.3.15.

The auditor received clarification about the reading rights of the laboratory results recorded in the TAL database as well as e-mail information about the updates recorded in the database. In addition to facility personnel, inspection veterinarians have reading rights of the TAL file.

E. coli sampling and records were determined to comply with requirements.

Foreign matter supervision and records

In terms of the foreign matter supervision program, only the antibiotic sampling program, research method and antibiotic research results were reviewed. Hannu Kangasmaa clarified the Excel-based randomisation program, the 0.2% of pigs selected for investigation, 30 – 40 pigs per week, as well as the research method of using *Bacillus subtilis* BGA indicator bacteria on pH 6 and pH 8 platforms. USDA's inspector inquired whether 'third part audits' are carried out concerning the antibiotic research. The facility's representative brought forth the information collected in Sikava and the notification obligations of medical officers and producers.

In 2014 antibiotic research had detected one suspicious result in February – March, and two suspicious results in November. All resamples had however been found negative.

Preproduction cleanliness inspection (SSOP/SOP) in the cutting plant

Ville Valli inspected the old cutting plant starting from the IPO facility; the space was clean. In the production area next to the carcass shipment facility some black stains on a cutting table; Tuomas Viita immediately ordered a new table top. 3 unwashed feed containers at the carcass shipment facility; Ville Valli instructed them to be washed. The farthest saw contained traces of meat in its conveyor rolls; cleaned by an ISS employee. A small piece was missing from the circular saw's blade; blade to be replaced. Tissue traces on the hoof cutter handle; to be cleaned immediately.

The rib line's raw cut conveyor's lower belt worn; to be changed immediately. On several tabletops, black traces detected; 6 table tops were immediately changed. Frayed / torn areas on the edges and / or surfaces of conveyors leading to round cuts, on conveyors of the rind processor, on Korea ribs, on silo 1, across line 3 and on ham belts of line 1 (a total of 8). Fibres or plastic can possibly get into the products from torn belts. Some belt edges clipped before starting production, rind processor removed from operation and other belts have been promised to be changed as soon as new belts arrive.

There was rust around the fixing screws of bending press protective plates; all must be fixed. Meat waste found on lower supports of work table next to rind processor; cleaned by ISS employee.

Traces found on SOP surface of vacuum packer's rolls; cleaned immediately. Mold under the protective plastic of container crane operating switch; protective plastic promised to be changed immediately.

Condensation on the lower surfaces of silo work tables, which has been dried immediately. In the silo area two containers were directed for washing because the auditor suspected that something had fallen loose from an above roll conveyor on the basis of white residue on the bottom of one of the containers.

The container crane's wet railing was dried and an attached piece of plastic was cut away immediately.

Meat residue on a screw on S-1 conveyor, which was immediately cleaned by an ISS employee. A small container still contained some water; Ville Valli instructed it to be rewashed.

Inside a blender the scraper support had ground a mark on the wall and possibly loosened pieces of metal into the produce.

In some air bags small splatter was detected due to washing; Ville Valli instructed the air bag next to the blender to be washed after covering up the blender. Ice around the dry ice supply pipe; the auditor

advised the piping to be insulated. Condensation on the spray nozzle; an employee dried the equipment. Black ribs conveyor still wet; a cleaning company employee dried it. Fat and meat splatter on the back plate of the 2-line's washing basin, cleaned by ISS.

A tar clot was found on the edge of the cutting dropper conveyor and tar flakes on its surface; old dirt on the upper surface of the droppers guiding iron. The cleaning company washed the location again and veterinarian Marja Fossi remained on location to inspect it before starting production.

The general cleanliness level was deemed good on the basis of the cleaning inspection. Corrective measures were appropriate.

The maintenance program was faulty in terms of the conveyor belt condition and replacement, detection of the worn metal surface in the blender and tracking the circular saw blade's condition.

Supervision of SSOP and SPS/SOP activities and non-standard codes of conduct in the carcass shipment facility, cutting plant and slaughterhouse during production

The carcass shipment facilities were tidy and clean. In warehouse 152 there was a large ceiling area with flaking paint from the shocker's door towards the slaughterhouse. No carcasses were moved in that area. In warehouse 155 carcasses directed to hair removal were stored on a separate rail. A dirty crane hood in the warehouse which was promised to be changed immediately. Tar in an airbag.

In the cutting house Ville Valli performed an inspection during production. In the reception area there was water on the protective plastic of one container; the plastic was cleaned immediately. The cutters' knife racks were tidily hung, 2 clean knives in the racks. The hairy part of the chain leg leads s.e., the leg in question is turned into animal feed. The feed containers were correctly marked.

Water was dripping from the box cutting plant's bone strip protective plate onto the walkway below; adjacent table 21 was cleared immediately and the area dried.

The auditor noticed a battered box, no. 3982, which the foreman removed from use. A relatively large condensation drop was found on table 11 wire protection plate at the box cutting plant's middle row. The line workers stopped cutting, the line was cleared and the contents of the meat containers in the area were directed to feed production. The condensation was dried and veterinarian Marja Fossi supervised the execution.

In the strip cutting plant the auditor observed at length the working practices of workers at cutting tables 1-2 and 2-3. On request, Tuomas Viita clarified the air bag cleaning program and washing frequencies.

In the slaughterhouse Jari Palomäki carried out a production hygiene inspection. He gave one meat inspector a beard protector and advised the organ hanger in use of headgear and washing of hands after adjusting the headgear.

There were leaking water hose connections next to the hanging point; the facility promised repairs without delay. A yellow spade was hung on the apron hanger; the foreman moved it to its proper place and promised to advise the cleaner.

Kenneth Witek asked about the program for certifying the cutting robot's sterilisation water. The alarm system and digital display by Atria Tekniikka were demonstrated, but the auditor was not convinced. A weekly tracking record is not sufficient to ensure that the temperature is always above +82°C. The reporting provided by the system should be further developed.

The auditor inquired whether the side rail is 'rail out'. Irmeli Sippola explained that according to EU legislation a meat inspector can approve healthy carcasses, but the carcasses on the side rail are approved by an inspection veterinarian.

The implementation of the SSOP/SOP program during production in the carcass shipment facility, cutting plant and slaughterhouse was according to requirements.

Tracking the slaughterhouse CCP

Jari Palomäki tracked the cleanliness of 10 carcasses in the post-inspection area at 9:50 – 9:52. He finally obtained the Trichinella number (787) of the tracked carcass from the system based on the carcass' hock number (7426) and recorded the tracking results immediately.

The CCP tracking and records were in accordance with the program.

Tracking E. coli sampling

Kari Sihto and Hannu Kangasmaa collected an E. coli swab sample in warehouse 154A, rail 6 from a carcass with the Trichinella number 565 at 8:30, according to instructions.

Tracking salmonella sampling

Kari Sihto collected a salmonella swab sample from carcass 6279 according to instructions at 8:35.

Implementation of animal welfare inspection program

In the piggery the unloading of pigs in stalls 16 – 17 was observed, beginning at 10:10. The herding was calm and all the animals were moving well. The auditor asked about the pig feeding program and implementation which were explained to him. Live inspection records were inspected in the piggery veterinarian's office.

The separation instructions according to 0000 stamping were reviewed and ways of keeping dead or euthanised animals from ending up in consumption were clarified. The procedures of opening the carcasses were clarified and Evira's special permit, dated 7.2.2003, for animal waste, colouring requirements were presented to the auditor first in speech and later in writing. Due to the animal waste processing system animal waste cannot end up as foodstuff.

Stunning and gas content (85% at minimum) tracking were demonstrated. Herding into the Butina system was observed. The slaughterhouse foreman presented the stunning results tracking system and the sting securing equipment. The auditor also asked about the use of the backup stunning equipment. Implementation of the animal welfare inspection program was appropriate.

Inspecting laboratory functions

The auditor inspected the FINAS accreditation certificate 20.1112, which is valid until 1.12.16. He also reviewed the results of FINAS's inspection. Hannu Kangasmaa clarified deviation corrections and notifications. The latest internal audit report was inspected. Seija Pihlajaviita presented the laboratory personnel's education registry and the performance appraisal evaluation program.

Sampling and pretreatment instructions (5.1.14), salmonella guidelines according to U.S. export requirements (25.1.14) and audit as well as accreditation seasons were reviewed. The correspondence of salmonella and E. coli results were compared with supervision results. It was determined that the latest Sa + results had been obtained from the lymph node samples of a sow (not in the slaughterhouse) in 2013, on 12.3., 15.7. and 16.10.13. There were no + results from swab samples during 2013 – 2015 or from pig lymph node samples.

The inspector also checked the deviation reports for E. coli limit value transgressions for 2014. The read rights for TAL database and e-mail reporting were brought up again.

In the salmonella laboratory the entire sampling process was reviewed. Instruction and forms were inspected.

A notice was issued on the tracking of incubators and coolers, because now temperature records are made only once a day.

The *S.abony* and *S.choleraesuis* control strains and negative *E. coli* incubation daily, however, shows that the incubators work as the used temperature results in growth.

The refrigerators are constantly monitored by Hg control gauges. The corrective coefficient had been neglected in the refrigerator temperature limits: calibration uncertainty in 4901 1137 is $\pm 0.3^{\circ}\text{C}$ and in 4851 1055 $\pm 0.6^{\circ}\text{C}$. The laboratory promised to fix the temperature limits without delay.

Autoclave temperature checks and verifications appropriate.

Seija Pihlajaviita presented QFY's self-monitoring document update and approval system.

Observations and grievances that resulted in procedures to be tracked in future inspections

3. Evira's auditor issued the facility a warning of revoking export rights during inspection due to shortcomings in the cutting plant's maintenance program.

The facility's conformity with requirements and fulfilling export conditions

4. The inspection veterinarian estimated that the facility will fulfil its requirements and export conditions in terms of inspected topics after corrective procedures have been implemented. The inspection veterinarian wrote a grievance report for the facility concerning the cutting plant's conveyor belt maintenance program on 10.3.15. The inspection veterinarian notified the facility about the inspection observations on 11.3.15, in the supervision report for week 11 and in the inspection review on 20.3.15.

Evira
IMPORT, EXPORT AND ORGANIC CONTROL (RALU)
Import and Export Department

Date	Reg. no.	Page(s)
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Senior Inspection Veterinarian
Marja-Riitta Mäkelä
HKScan Finland Oyj
Teollisuuskatu 17
30420 FORSSA, FINLAND

AUDIT REPORT

For your consideration and future procedures, The Finnish Food Safety Authority dispatches the following annexed audit report, written for the audit of the supervisor of the facility approved for U.S. exports at HKScan Finland Oy's facility no. 18 in Forssa, Finland on the 12th of March 2015.

Temporary Head of Unit
Import, export and organic control

Eeva-Liisa Taskinen

Senior Inspector
Import, export and organic control

Marianne Peltomaa

Annex Audit report Reg. no. 79/0477/2015

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Date 02.04.2015 Reg. no. 79/0477/2015

Audit of supervisor of facility approved for U.S. exports

Name of facility: HKScan Finland Oy, Forssa, Finland

Facility approval number: 18

Supervising authority: Governmental inspection veterinarian

Audit date: 12.3.2015

Auditor: Senior Inspector Marianne Peltomaa

Present at audit: USDA auditor Kenneth E. Witek
Senior Inspection Veterinarian Marja-Riitta Mäkelä
Inspection Veterinarian Timo Laita
Quality Manager Maarit Vähärautio
Senior Inspector Tua Goldman

Signature:

General

The audit in question was carried out in conjunction with the U.S. Department of Agriculture's (USDA) inspection. The inspection was carried out by Kenneth E. Witek.

1. AUDIT PLAN

Topics for audit plan

The Finnish Food Safety Authority's (Evira) audit plan topics for the month were:

1. the slaughterhouses and cutting plant's SPS/SOP program for codes of standard and non-standard conduct
2. the cutting plant's HACCP program
3. the cutting plant's HACCP program's records
4. records of animal welfare inspections
5. pre-production cleanliness inspections in the cutting plant
6. functionality of the cutting house's incoming inspection / its supervision
7. inspection of the animal transport vehicle
8. carrying out animal welfare inspections
9. supervision of SSOP program implementation in the cutting house during production
10. inspection veterinarians' zero-tolerance inspection at the slaughterhouse
11. inspection veterinarians' supervision plan for the year 2015
12. inspection veterinarians' animal transport vehicle's hygiene inspection records
13. inspection veterinarians' ante mortem records
14. inspection veterinarians' other supervision records and plans for the requested parts

Audit plan follow-up topics

The follow-up topics in Evira's audit plan were tracking records and health marking stamps.

Audit plan additional topics

Evira's audit plan included the following additional topics requested by USDA FSIS auditor Kenneth E. Witek:

1. the slaughterhouses HACCP program
2. the slaughterhouses HACCP program records
3. the slaughterhouses and cutting plant's SSOP program and supervision records
4. shipping inspection program and records
5. verifying the laboratory's accreditation certificate
6. E. coli research program and sampling research result records
7. Salmonella research program and sampling research result records
8. SPS/SOP program implementation controls during production in the cutting plant

9. SSOP program implementation controls during production in the slaughterhouse
10. SPS/SOP program implementation controls during production in the slaughterhouse
11. appropriateness of tracking and verifying CCP in the cutting plant
12. appropriateness of tracking and verifying CCP in the slaughterhouse
13. education information of inspection veterinarians and meat inspectors and managing temporary workers
14. keeping and issuing U.S. export certificates
15. carcass health markings
16. grievance reports by inspection veterinarians
17. inspection veterinarians' supervision of post mortem inspections by meat inspectors

2. SUPERVISION PLAN

Supervision plan topics

The inspection veterinarians' supervision plan topics for the day were the same as the topics in the audit plan in terms of inspected topics.

Supervision plan follow-up topics

There were no follow-up topics in the inspection veterinarians' supervision plan.

Supervision plan additional topics

The inspection veterinarians' supervision plan additional topics were the same as the additional topics in the audit plan.

3. OBSERVATIONS MADE DURING AUDIT

The inspection veterinarians' supervision plan

Of the inspection veterinarians' supervision plan, weekly supervision plans were audited.

The inspection veterinarians' supervision records

Of the inspection veterinarians' supervision records, weekly supervision records were audited.

Of the inspection veterinarians' supervision records, grievance report records were audited.

Of the inspection veterinarians' supervision records, ante mortem records were audited.

Of the inspection veterinarians' supervision records, the educational information of inspection veterinarians and meat inspectors as well as temporary worker management were audited.

The tracked inspection veterinarians' tracking records were not audited at this time, but instead postponed to the May – June audit.

The inspection veterinarians were asked to explain the keeping and issuing of U.S. export certificates. The auditor had nothing to remark concerning the keeping or issuing of U.S. export certificates.

The activities of inspection veterinarians

The inspection veterinarian carried out a zero-tolerance inspection of manure deposits at the slaughterhouse final cleaning facility.

The inspection veterinarian inspected the meat inspectors' post mortem inspection. The meat inspectors performed appropriately at all inspection locations. The inspection veterinarian had no remarks concerning the carrying out of meat inspection.

The auditor requested that the inspection veterinarians explain the keeping and issuing of U.S. export certificates. The auditor had nothing to remark concerning the keeping or issuing of U.S. export certificates.

4. THE ACTIVITIES OF INSPECTION VETERINARIANS: INSPECTING THE FACILITY'S SELF-MONITORING PROGRAMS, ACTIVITIES AND RECORDS

Self-monitoring programs

FSIS auditor Kenneth E. Witek (hereafter the auditor) requested that the facility's representative demonstrate the slaughterhouses and cutting plant's HACCP programs. The facility's representative demonstrated the programs. The HACCP programs for the slaughterhouse and the cutting facility include product descriptions, flowcharts, hazard analysis and HACCP plans. The auditor had no remarks concerning the HACCP programs.

The auditor requested that the facility's representative demonstrate the slaughterhouses and cutting plant's SSOP programs. The facility's representative demonstrated the programs. The auditor had no remarks concerning the SSOP programs.

The auditor requested that the facility's representative demonstrate the shipping inspection program. The facility's representative demonstrated the program. The auditor had no remarks concerning the program.

The auditor requested that the facility's representative demonstrate the E. coli research program. The facility's representative demonstrated the program. There was discussion concerning the random selection of the sample carcass. The sample carcass is the one with a running number five integers greater than the randomly selected carcass. The auditor had no remarks concerning the program.

The auditor requested that the facility's representative demonstrate the salmonella research program. The facility's representative demonstrated the program and said that the facility collects annual

salmonella samples in accordance with the national salmonella control program. The amounts of samples collected in 2015 are: 1129 swab samples and 1129 lymph node samples. The samples are collected according to Evira's guidelines and the research methods are approved by USDA and Evira. The auditor had no remarks concerning the salmonella research program.

The facility's representative presented the HKScan Finland Oy laboratories' accreditation certificates to the auditor. All HKScan laboratories hold the same accreditation. Samples from the Forssa facility are studied in three HKScan laboratories: Vantaa, Eura and Forssa. The auditor had no remarks concerning the accreditation certificates.

Self-monitoring program records

The auditor requested that the facility's representative present the records for the slaughterhouses and cutting plant's HACCP programs from 90 days back. The facility's representative presented the records. The records for the most recent deviation and its associated corrective measures were also reviewed. The latest deviation had occurred in the summer of 2013. Some record entries were found to be outdated or written over previous entries. The signature of the correction implementer was also missing in a few entries. The inspection veterinarian wrote a grievance report for the facility due to these observations. The auditor had no other remarks concerning the records of the slaughterhouses and cutting plant's HACCP programs.

The auditor requested that the facility's representative present the slaughterhouses and cutting plant's preoperative and operative SSOP records for the last 90 days. The facility's representative presented the records. The records were in order. The auditor had no remarks concerning the SSOP records.

The auditor requested that the facility's representative present the shipping inspection records. The records were in order. The auditor had no remarks concerning the records.

The auditor requested that the facility's representative present the records for the E. coli research program results. Sample results were inspected for the years 2014 and 2015. In this period there were two limit value transgressions, one in February of 2015 and the other in March of 2015. The second transgression had occurred in the 11th sample after the previous transgression. Since the 13 samples following a transgression are required to be under the limit value, a deviation report had been written for the slaughterhouse concerning the issue. The auditor had no other remarks concerning the E. coli research result records.

The auditor requested that the facility's representative present the records for the salmonella control program results for the year 2015. The facility's representative presented the records. The records were in order. In 2015 there had been no positive salmonella samples so far. The auditor had no remarks concerning the salmonella control program result records.

Implementing self-monitoring programs

The auditor inspected the way the facility implemented the SSOP program's and SPS/SOP instructions' implementation controls in the slaughterhouse and cutting plant during production. Several SSOP and SPS/SOP faults were detected in the slaughterhouse and cutting plant. The faults are recorded in more detail in the inspection veterinarian's grievance report. The facility's representatives immediately corrected the grievances at SSOP locations and the SPS/SOP location grievances were either fixed

immediately or listed as needing corrections. The auditor had no remarks concerning the SSOP program's and SPS/SOP instructions' implementation controls during production.

The auditor inspected the way the facility's representatives carried out the tracking and verification of the slaughterhouses CCP. The facility's representatives inspected 15 pig carcasses for manure and intestine contents after the final inspection. In one of the carcass halves dirt resembling manure was detected on the ham. The facility stopped the line, marked the half and removed the dirty part from the carcass. The dirt, however, turned out to be burnt hair and not manure. The auditor had no remarks concerning the facility's representatives' CCP tracking and verification.

In conjunction with CCP tracking and verification inspection, it was observed that one of the carcass halves was unclearly stamped for health marking (the stamp was missing half of the number eight). Without supervisor interference the unclearly stamped half would have proceeded down the line. Another proper health marking was stamped next to the unclear one. Carcass stamping has been a problem at the facility (as observed in November 2014 and January 2015), so the facility was issued a warning of losing its U.S. export rights (NOID).

The auditor inspected the way the facility's representatives carried out the tracking and verification of the cutting plant's CCP. The facility's representatives measured meat temperatures at the packing plant's CCP location. The thermometers of the representatives displayed a temperature difference of 0.8 degrees, which is not acceptable (the acceptable thermometer temperature difference is no more than 0.5 degrees). The verifier changed his thermometer, after which the displayed re-measured temperature difference was acceptable. The inspection veterinarians filed a grievance report concerning the faulty functioning of the verification thermometer to the facility. After this, the auditor had no remarks concerning the facility's representatives' CCP tracking and verification.

The auditor inspected the functioning of the cutting plant's incoming inspection and its supervision. The auditor had no remarks concerning the incoming inspection or its supervision.

5. SUPERVISION ASSESSMENT

The weekly supervision plans and records were in accordance with Evira's guideline (18511/1). The auditor also had no remarks concerning them.

The inspection veterinarians have written grievance reports according to Evira's guideline (18511/1) and no remarks were made concerning them. The auditor also had no remarks concerning them.

No remarks were made concerning the ante mortem records presented by the inspection veterinarians. The auditor also had no remarks concerning the records.

The performance of the inspection veterinarians as well as their questions and remarks to the facility's representatives were found to be appropriate.

The inspection veterinarian's inspection report was properly written and was in accordance with Evira's guideline (18511/1) concerning inspection reports.

Follow-up topics for next audit

The audit did not detect any faults in the inspection veterinarians' performance that would require follow-up.

The next audit (NOID audit) audits how the facility has corrected the grievances detected during the USDA audit and how the inspection veterinarians have tracked them. The correction of grievances will be audited in a NOID audit within 30 days of the USDA audit.

The audit plan topics that were not audited at this time will be postponed to the May audit.

6. THE FACILITY'S CONFORMITY WITH REQUIREMENTS AND FULFILLING EXPORT CONDITIONS

The audit detected an unclear health marking on one carcass half. The facility has received notifications concerning unclear or wrongly numbered health markings in November 2014 and January 2015. Thus, in conjunction with the audit the facility was issued a warning of revoking export approval (NOID) by the Finnish Food Safety Authority due to recurring unclear health markings. The audit also discovered other grievances which are listed in the Warning concerning the revocation of U.S. export rights (dated 16.3.2015) and the correction of which will be audited in a NOID audit within 30 days of the USDA audit.

Control Department

Date
14.3.2015

Reg. no.
79/0477/2015

Inspection report of facility approved for U.S. exports

Name of facility HKScan Finland Oy, Forssa, Finland	Approval number of facilities 18
Supervising authority Finnish Food Safety Authority Evira	
Inspector Inspection Veterinarian Marja-Riitta Mäkelä	
Inspection date 12.3.2015	

Present at inspection

Dr. Kenneth E. Witek
Senior Inspector Marianne Peltomaa
Senior Inspector Tua Goldman
Inspection Veterinarian Timo Laita
Quality Manager Maarit Vähärautio, HKScan Finland Oy, Forssa, Finland

To be notified

HKScan Finland Oy
Evira

Inspector's signature

Evira

Inspection topics

1. Topics of the day's supervision plan
 - 1.1 The slaughterhouses and cutting plant's SPS/SOP program in terms of codes of standard and non-standard conduct
 - 1.2 The cutting plant's HACCP program
 - 1.3 The cutting plant's HACCP program records
 - 1.4 Animal welfare inspection records
 - 1.5 Preproduction cleanliness inspection implementation in the cutting plant (transferred from January)
 - 1.6 Functionality of the cutting plant's incoming inspection / its supervision
 - 1.7 Inspection of the animal transport vehicle
 - 1.8 Carrying out the animal welfare inspection
 - 1.9 SSOP program's implementation supervision in the cutting plant during production
2. Audit plan additional topics
 - 2.1 The slaughterhouses HACCP program and supervision records
 - 2.2 The facility's SSOP program and supervision records
 - 2.3 The shipping inspection program and records
 - 2.4 Verifying the laboratories' accreditation certificates
 - 2.5 E. coli research program and records of sample collection research results
 - 2.6 Salmonella research program and records of sample collection research results
 - 2.7 SPS/SOP program implementation supervision in the cutting plant during production
 - 2.8 SSOP program implementation supervision in the slaughterhouse during production
 - 2.9 SPS/SOP program implementation supervision in the slaughterhouse during production
 - 3.0 Appropriateness of cutting plant CCP tracking and verification
 - 3.1 Appropriateness of slaughterhouse CCP tracking and verification

Observations made during the inspection

3. Self-monitoring program and records

3.1 Cutting plant HACCP program and supervision records

The quality manager demonstrated the cutting plant's HACCP program. The program includes a product description, a flow chart, hazard analysis and a HACCP plan. No remarks concerning the cutting plant's HACCP program.

At the same time the records from 90 days back were inspected. The record entries for the most recent deviation and associated corrections were reviewed. The latest deviation in the cutting plant was from the summer of 2013. It was observed that some corrections were made over existing record entries, the entry reinforced and/or signature of the implementer of correction was missing. A grievance report was filed with the facility concerning this observation (grievance report 11/2015). No other remarks concerning the records.

4. Implementation of self-monitoring programs

4.1 Functioning of the cutting plant's incoming inspection / its supervision

The incoming inspection location of the cutting plant's initial cutting facility was inspected together with the supervision efficacy at the inspection location. The employee records detected faults into a table. The department foreman sends the fault table every day via e-mail to, i.e. the slaughterhouse department head, the slaughterhouse foremen and the inspection veterinarians.

No remarks were made concerning the cutting plant's incoming inspection or the functioning of its supervision.

4.2 SSOP program's implementation control in the cutting plant during production

Activities in the cutting plant were observed during production. Several frayed or damaged meat conveyor belts were detected in initial cutting. In further cutting locations rust was discovered on an air duct (round faucet) above line 5 and on the air duct protection plate over the box rails. The meat rail switcher was rusted and the plastic coated switcher string was dirty and damaged. In the packing area, there was a dirty air duct over an open meat packing location. These observations resulted in filing grievance reports to the facility (grievance reports 2/2015, 4/2015 and 6/2015).

Inspection observations concerning the audit plan additional topics

5. Self-monitoring programs and records

5.1 The slaughterhouses HACCP program and supervision records

The quality manager demonstrated the slaughterhouses HACCP program. The program contains a product description, a flowchart, hazard analysis and a HACCP plan. No remarks on the slaughterhouses HACCP program.

At the same time records from 90 days back were inspected. The latest deviation and associated corrective measures record entries were also reviewed. The most recent deviation in the slaughterhouse had occurred in January 2014. The records were in accordance with guidelines. No remarks on the records.

5.2 The facility's SSOP program and supervision records

The quality manager demonstrated the facility's SSOP program. The program is clear and comprehensive. At the same time the slaughterhouses and cutting plant's operative and preoperative hygiene control records from 90 days back were inspected. The records were in order. No remarks on the SSOP program and records.

5.3 Shipping inspection program and records

The quality manager demonstrated the facility's shipping inspection program and associated records. The program and records were in order. No remarks concerning the program or records.

5.4 Verifying the laboratory's accreditation certificate

The quality manager presented the accreditation certificates for HKScan Finland Oy's laboratories. Sample from the Forssa facility are researched in HKScan Finland Oy's laboratories in Vantaa, Eura and Forssa. No remarks concerning the accreditation certificates.

5.5 E. coli research program and records of sample research results

The quality manager demonstrated the E. coli research program and the associated random selection of a sample carcass was discussed. The sample is collected once per working day from a refrigerated carcass. The sample pig is the one with a running number five integers greater than the randomly chosen carcass.

Sample results were reviewed for the years 2014 – 2015. There were two transgressions in 2015's results (February and March). After a transgression the following 13 samples should be below the limit value. The other transgression, however, had occurred at sample 11. A deviation report had been filed to the facility. No remarks concerning the slaughter hygiene program or its records.

5.6 Salmonella research program and records of sample research results

The quality manager demonstrated the facility's salmonella control program. The facility collects yearly salmonella samples to the extent required by the national salmonella control program. This year there had been collected 1129 swab samples and 1129 lymph node samples. Sample collection instructions are in accordance with Evira's guidelines. Research methods approved by Evira and USDA.

The salmonella control program's result records were reviewed for the year 2015. The records were in order and no positive salmonella samples had been detected. No remarks concerning the salmonella program or its records.

6. Implementation of self-monitoring programs

6.1 SPS/SOP program implementation supervision during production in the cutting plant

The cutting plant's activities were observed during production. In further cutting, in the first cutting location on line 8 a worker touched a portable ladder with protective gloves on and continued working wearing the same gloves. The supervisor ordered the gloves to be changed. There were several steel basins with broken corners in the cutting plant. In the packing facility, there was sealing coming loose from the edges of the box rail's wall opening, and a half piece missing from a conveyor. The previous observations were recorded in grievance reports (grievance reports 3/2015, 7/2015 and 8/2015).

In initial cutting, there was a separate saw standing next to the line with a partly broken (loose crumbs) plastic covering (edge). In the cooling facility next to initial cutting, there was a broken plinth by the door and a hole in the air duct on the wall. There was also a dirty thermometer in a wall rack.

Going into the packing facility there was a dried piece of meat in the elevated box rail's structure (on the cutting plant side) by the door. The previous observations were recorded in the facility's deviation table.

6.2 SSOP program implementation supervision during production in the slaughterhouse

The slaughterhouses activities were observed during production. There was some dirt on the ceiling above the intestine and carcass lines (at two different locations on the slaughter line). The observation was recorded in a grievance report (grievance report 9/2015).

6.3 SPS/SOP program implementation supervision during production in the slaughterhouse

The slaughterhouses activities were observed during production. There was an open inlet on the wall by the side rail. There were two pipes with partly loosened tapings on the same wall. The previous observation has been recorded in the facility's deviation table.

6.4 Appropriateness of cutting plant CCP tracking and verification

The cutting plant's department head inspected temperature measurements carried out at the packaging facility's CCP location. He measured the meat temperature with his own verification thermometer. The measurement revealed that the worker's and department head's thermometers displayed a difference of +0.8 degrees C. The department head retrieved another thermometer. The re-measurement displayed an acceptable temperature difference between the thermometers (no more than 0.5 degrees C). The verification thermometer's failure to function was recorded in a grievance report (grievance report 5/2015).

6.5 Appropriateness of slaughterhouse CCP tracking and verification

The slaughterhouse foreman's CCP tracking and the temporary department head's CCP verification were observed simultaneously. The foreman inspected 15 pig carcasses for manure and intestine contents after the final inspection.

In one carcass dirt was detected on the ham of the other carcass half. The line was stopped, the carcass marked with red tape and the dirty section removed from the carcass. Upon closer inspection of the dirty section it was decided that the dirt was not in fact, manure or intestine contents but burnt hair.

Tracking and verification took place, according to guidelines and no remarks were made concerning them.

In conjunction with the supervision it was noticed that a health marking stamped by hand by one of the employees was not clear enough. Another marking was stamped next to the unclear one. The automatic stamper was not in use due to repairs.

There have been earlier observations of unclear health markings. The supervisor had filed a grievance report in November 2014 and a similar problem had been noticed in the monthly audit of January 2015.

The supervisor immediately notified the facility that Evira will issue a warning of revoking U.S. export approval (NOID) due to the recurring nature of this problem.

The supervisor also filed a grievance report for the facility as the employee did not check the clarity of the stamp (grievance report 10/2015).

Observations and grievances resulting in procedures to be tracked in future inspections

7. The inspection did not cover all of the topics of the day's inspection plan, so the uninspected topics will be inspected during the next Evira audit.

- 7.1 The slaughterhouses and cutting plant's SPS/SOP program in terms of codes of standard and non-standard conduct
 - 7.2 Animal welfare inspection records
 - 7.3 Preproduction cleanliness inspections in the cutting plant (transferred from January)
 - 7.4 Animal transport vehicle inspection
 - 7.5 Implementation of animal welfare inspections
8. Grievance reports 2 – 11/2015. The facility is due to respond to these reports by 18.3.2015.
9. The grievances recorded in the deviation table will be tracked during normal weekly controls.

The facility's conformity with requirements and fulfilling U.S. export conditions

10. The facility does not sufficiently fulfil the requirements and export conditions set for it. The supervisor submits that RALU/Evira issue the facility a warning of revoking U.S. export approval (NOID).

Atria Suomi

RESPONSE

1 (1)

30.3.2015

RESPONSE TO THE NOID RECEIVED BY FACILITY 22 DURING ITS USDA AUDIT

In the USDA audit during a preproduction inspection on 10.3.15, 7 conveyor belts were detected in poor condition, with damaged surfaces or with frayed or chipped edges. In addition, wear marks were detected in a blender in the pig cutting plant.

1. Worn and damaged belts in the cutting plant

Response: the belts were removed from use or repaired before production was started. Belt inspections have been added into daily hygiene controls during production (operational SSOP and SOP). If faults are detected during the controls A-Tekniikka are informed immediately and they will carry out corrective procedures. In addition, the condition of the belts is inspected on an inspection tour performed four times a year by the cutting plant's foreman and A-Tekniikka's facility maintenance person. During the tour the condition of each belt is recorded and if there are any shortcomings A-Tekniikka will rectify them. The q-tour reports will be added to the TAL database.

2. Blender wear marks

Response: production inspected whether metal flakes or chips are possibly mixed into the produce by the blender. Before production was started the blender was run empty to determine whether the flanges come into contact with the edges and if metal is loosened while the blender is running. Based on a visual inspection, the flanges did not come into contact with the edges while the device was running. A-Tekniikka used a feeler gauge to measure the gap between the flanges and the inside wall. No contact between the flanges and the wall was detected. In 2010 the blender bearings have broken down, during which incident the flanges have come into contact with the device's edges. The wear marks are due to this incident. During production a total of seven samples was collected every thirty minutes or so, which were first examined by an x-ray machine and then by a metal detector. No metals were detected in the produce by these tests.

Seinäjäki, Finland 30.3.2015

Tuomas Viita

Production Manager
A-Pekoni Nurmo Oy

HKScan Finland Oy
Teollisuuskatu 17

30420 Forssa, Finland
Maarit Vähärautio
Quality Manager

Annex IV

HKSCAN

RESPONSE

Marianne Peltomaa
Import, Export and Organic Control
Evira
Mustialankatu 3
00790 Helsinki, Finland

30/03/2015 1 (3)

RESPONSE TO GRIEVANCES IN THE REPORT OF THE WARNING OF REVOKING U.S. EXPORT RIGHTS (Reg. no. 668/0477/2015)

1. The facility has had problems with the stamping of health markings.
 - **Agreed procedures. Scheduled for April 2015. Responsible person slaughterhouse department head Jari Koivisto**
 - Procedures agreed upon after U.S. audit
 - i. Employees were retrained for the task immediately after the audit. The employees are instructed to always check the stamp after stamping and to re-stamp the carcass if the stamp is unclear. The stamp is pressed on the ham on an even surface. Compiling a written work instruction of hand stamping was also agreed upon.
 - The following procedures have been implemented and agreed upon after the earlier grievance reports (5.11.2014 and 28.1.2015)
 - i. Inspecting the stamping device condition, cleaning and replacing the stamp head and ensuring maintenance. More specific maintenance procedures are in a separate document which can be annexed to the response if necessary.
 - ii. Supervising the health marking in the slaughterhouse so that the stamp is inspected at the beginning of the day and 6 times during the day (in conjunction with monitoring). Records will be kept on the monitoring form.
 - iii. In initial cutting before cutting the health markings of 10 carcasses slaughtered the day before and taken from different booths will be inspected.
 - iv. Hand stamping until the device is in order starting 19.2.2015
 - v. Self-monitoring will be changed so that there is only one stamp.
2. Several damaged conveyor belts were detected in the cutting plant
3. Rust was discovered in the cutting house superstructures above the product

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4. There were holes in two places on the cutting plant floor

2 (3)

HKSCAN

5. The packing facility's canvas air conditioning bag looked dirty
6. A loose seal on the edge of the packing facility's box rail, a piece missing from conveyor
7. Water dripping from the carcass refrigerating facility's ceiling
8. Damaged plinth in the cooling facility and a hole in the air duct on the wall

Procedures agreed for points 2 – 8 and schedules

- Re-evaluation of maintenance program. Evaluation carried out 26.3. and 27.3.2015. The following procedures agreed upon on the basis of evaluation. Procedures **scheduled for April 2015.**
 - Maintenance will now carry out a daily control tour of each department to inspect the condition of conveyors and superstructures. Records will be kept of inspections and corrections.
 - Maintenance will report the inspection results in the weekly meeting by department.
 - A separate weekly meeting agenda point for structural issues. At least the following to be covered: conveyor condition, condensation, rust, other structural faults such as floor condition and plinths.
 - Cleanliness inspectors will inspect the conveyor condition every morning. The inspection and procedures will be recorded in the cleanliness inspection form. Other structural deficiencies and procedures will be similarly recorded. Self-monitoring instructions to be updated.
 - Cleanliness inspection records and their recorded grievances will be discussed at the weekly meeting and, if necessary, corrections and their schedules agreed upon.
 - As for the air conditioning bags, maintenance will inspect them and remove the most worn and dirty ones from use.
 - Operational supervision is part of hygiene controls performed by management. Supervision form will be changed so that structures are a separate issue. Quality manager responsible.
9. Cleanliness shortcomings; slaughterhouse ceiling; dirty structures above carcasses and intestines.

Preventive measures, schedule and responsible persons

- Reassessment of cleanliness program. Assessment carried out 26.3. and 27.3.2015. The following procedures agreed upon on the basis of assessment. Procedures **scheduled for April 2015.**
 - i. Washing frequency changed; structures above chuck conveyor now washed once a week
 - ii. The spot in question was scheduled for washing on the previous morning wash. It was decided that now the procedures agreed for mornings will be signed as completed at the weekly meeting. A separate agenda topic to help remember this
 - iii. Cleanliness inspectors are instructed to inspect the superstructures at critical locations such as above the chuck conveyor and at the fat separation equipment. Quality manager responsible

- iv. Operational supervision is part of hygiene controls performed by management. Supervision form will be changed so that structures are a separate issue. Quality manager responsible

3 (3)

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HKScan Finland Oy

Maarit Vähärautio
Quality Manager

Evira
IMPORT, EXPORT AND ORGANIC CONTROL (RALU)
Import and Export Department

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Inspection Veterinarian
Marja Fossi
Atria Oyj
P.O. Box 117
60101 SEINÄJOKI, FINLAND

AUDIT REPORT

For your consideration and future procedures, The Finnish Food Safety Authority dispatches the following annexed audit report, written for the audit of the supervisor of the facility approved for U.S. exports at Atria Oy's facility no. 22 in Nurmo, Finland on the 7th of April 2015.

Temporary Head of Unit
Import, export and organic control

Beata Meinander

Senior Inspector
Import, export and organic control

Marianne Peltomaa

Annex Audit report Reg. no. 76/0477/2015

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Date 13.04.2015 Reg. no. 76/0477/2015

Audit of supervisor of facility approved for U.S. exports

Name of facility: Atria Oy, Nurmo, Finland

Facility approval number: 22

Supervising authority: Governmental inspection veterinarian

Audit date: 7.4.2015

Auditor: Senior Inspector Marianne Peltomaa

Present at audit: Inspection Veterinarian Marja Fossi
Production Manager Tuomas Viita
Quality Manager Katja Lehtinen
Slaughterhouse Head Sami Roiha
Quality Director Tiina Myllylä
Intern Suvi Viinamäki

Signature:

General

The audit in question was a follow-up NOID audit to USDA audit conducted on 10.3.2015 and audited only the corrections to grievances resulting in the NOID (warning of revoking export rights).

AUDIT OBSERVATIONS

1. The cutting plant's work instructions have been updated 31.3.2015. The facility's representative presented the addition therein according to which the condition of the conveyor belts will be inspected daily by both shifts as part of operational hygiene controls and four times a year on a larger scale inspection tour by the cutting plant foreman and the facility maintenance person from A-Tekniikka. The tours will be documented in an Excel table and made visible to the inspectors. On the tours the condition of each belt will be recorded for each conveyor, and if there are faults in the belt conditions A-Tekniikka will carry out the necessary corrective measures. The facility has conducted the first large scale conveyor belt condition inspection on 2.4.2015. Deviant belts (fraying, holes, etc.) had at that time been recorded in the table. By the next inspection the table will be updated to include all of the belts with machine place numbers (belts in good condition will also be individually marked in addition to the damaged belts). The inspection veterinarian had no remarks concerning the work instructions or the conveyor belt condition control program.

The condition of all the conveyor belts was inspected by the inspection veterinarian, cutting plant foreman, production manager, quality director and A-Tekniikka's foreman during the large scale conveyor belt inspection tour of the cutting plant on 2.4.2015. The inspection veterinarian and the facility's representatives at that time determined that all of the belts that had been deemed to be in poor condition during the USDA audit of 10.3.2015 were now replaced and in good condition. The tour, however, discovered a number (c. 10) of other conveyor belts in poor condition. These belts were ordered to be replaced or their edges trimmed without delay. Records were entered into the tour's Excel table concerning the belts that needed replacement or repairs. The tour also determined that the other grievances detected during the 10.3.2015 audit were corrected (more detailed information about these grievances can be found in the inspection veterinarian's inspection report).

The NOID audit of 7.4.2015 determined that the conveyor belts deemed to be in poor condition during the USDA audit of 10.3.2015 were all in good condition, as did the facility's representatives' and the inspection veterinarian's cutting plant conveyor inspection tour of 2.4.2015.

2. The facility presented a report concerning the blender's wear markings. The device had been run empty before starting production, and no contact with the walls or any kind of scraping noise had been detected. A-Tekniikka used a feeler gauge to measure the gap between the blender's inside wall and the mixer flange. The gap was 1 mm. The device's maintenance history revealed that the device had broken down in 2010 (broken blender bearings), which had caused flange contact with the device's edges. The wear markings are a result of this breakdown.

The facility had also collected seven four kilogram produce samples every 30 minutes and analysed them by an Intellisense x-ray machine and a metal detector. No metal deposits were

detected in the produce. The inspection veterinarian thinks that the facility's clarification and report were thorough and sufficiently demonstrated that the device does not cause a product safety hazard.

The NOID audit observed the device's functioning during production. An audiovisual inspection did not present evidence that the blender's flanges were in contact with the walls.

THE FACILITY'S CONFORMITY WITH REQUIREMENTS AND FULFILLING EXPORT CONDITIONS

Evira's representative agreed with the inspection veterinarian's assessment that after the corrective measures taken to address the grievances detected during the 10.3.2015 USDA audit, the facility sufficiently fulfils the requirements and export conditions set for it in terms of the inspected topics.

Evira

FINNISH FOOD SAFETY AUTHORITY
MEAT INSPECTION
Inspection Veterinarian Marja Fossi
c/o Atria Oy, P.O. Box 900, 60060 ATRIA, FINLAND

Date 7.04.2015 Reg. no. 76/0477/2015

Audit of supervisor of facility approved for U.S. exports

Name of facility: Atria Oy, Nurmo, Finland

Facility approval number: 22

Supervising authority: The food safety authority's inspection veterinarian

Audit date: 7.4.2015

Auditor: Corresponding Senior Inspection Veterinarian Marja Fossi

Present at audit: Senior Inspector Marianne Peltomaa, Evira
Production Manager Tuomas Viita
Slaughterhouse Head Sami Roiha
Quality Manager Katja Lehtinen
Quality Director Tiina Myllylä
Intern Suvi Viinamäki

Signature:

Audit plan follow-up topics:

Inspection of corrections to grievances detected during the audit of 10.3.2015 and resulting in the warning of revoking U.S. export rights issued 16.2.2015 (NOID audit). The inspection targets were the condition and systematic maintenance of the condition of the cutting house conveyor belts as well as the risk of metal ending up in consumption due to a worn blender.

Inspection observations

1.

Tiina Myllylä presented the new cutting plant work instructions, updated 31.3.2015. The work instructions describe the controlling of the condition of conveyor belts daily by both shifts and a control tour of all conveyors that takes place four times a year. The tours are documented in an Excel table that is added into the TAL database for the supervisor to see. She presented the results table for the first inspection tour of 2.4.2015. Belts with deviations had been entered into the table. The table will be expanded to cover all belts with machine place numbers by the next inspection.

The supervisor had no remarks concerning the work instructions and the belt condition control program.

On Thursday, 2.4.2015, the signed supervisor Marja Fossi, Tiina Myllylä, Tuomas Viita, foreman Jarmo Välimäki and A-Tekniikka's foreman Juha-Pekka Laine conducted an inspection of the condition of all conveyor belts in the cutting plant. The belts deemed to be in poor condition in the 10.3.2015 audit were now changed and in good condition. The tour, however, found c. 10 other belts in poor condition. These belts were ordered to be changed and/or the edges trimmed without delay. Tiina Myllylä and the foremen immediately drew up a preliminary Excel table that will serve as the foundation for later quarterly inspections once supplemented. The same tour determined that the other grievances detected during the 10.3.2015 audit (a damaged circular saw blade, rust on the bending machine protective plate screws, mould under the container crane's keyboard plastic cover) were fixed.

The cutting plant tour conducted during this additional audit found the conveyor belts in good condition. It was also verified that the other grievances detected during the 10.3.2015 audit (a damaged circular saw blade, rust on the bending machine protective plate screws, mould under the container crane's keyboard plastic cover) were fixed.

2.

Tiina Myllylä presented a report concerning the wear marks in the blender. The device's functionality had been inspected by running it empty. No contact with the walls had been detected. The maintenance history revealed that the device had suffered a breakdown in 2010 which was the probable cause of the wear marks. The device's functionality had been additionally inspected by collecting samples from the product batches blended in the blender. The sample had been investigated by an x-ray machine and a metal detector. No metal had been discovered. The gap between the blender wall and the blender flange was measured with a feeler gauge. The gap was 1 mm.

The supervisor determined that the clarification provided by the facility's representatives and its associated report was thorough and sufficient to show that the device does not constitute a product safety hazard.

During this additional audit cutting plant tour the blender was observed while running. Based on a sensory evaluation, the blender flanges did not come in contact with the blender inner walls.

The facility's conformity with requirements and fulfilling export conditions

The inspection veterinarian estimated that the facility has appropriately fixed the grievances detected during the audit of 10.3.2015 and fulfils the requirements and export conditions set for it in terms of the inspected topics.

PORK ASSORTMENT BLENDING – MAPPING THE RISK OF POSSIBLE FOREIGN BODIES

The USDA audit of 10.3.2015 detected wear marks in the pig cutting plant's blender. This led to an investigation of whether metal chips or flakes are possibly loosened into the assortments from the blender. On the morning of Friday 27.3., before production was started, the blender was run empty to determine whether the flanges come into contact with the sides of the device loosening pieces of metal. The test was begun at 5:45 and was continued for about 15 minutes. Pictures were taken during the test to visualize the situation.



Picture 1. S1 blender

Picture 1 shows the gap between the blender wall and axis. According to a visual inspection the part did not come into contact with the wall and no sounds were heard during operation.

ATRIA SUOMI

MEMO

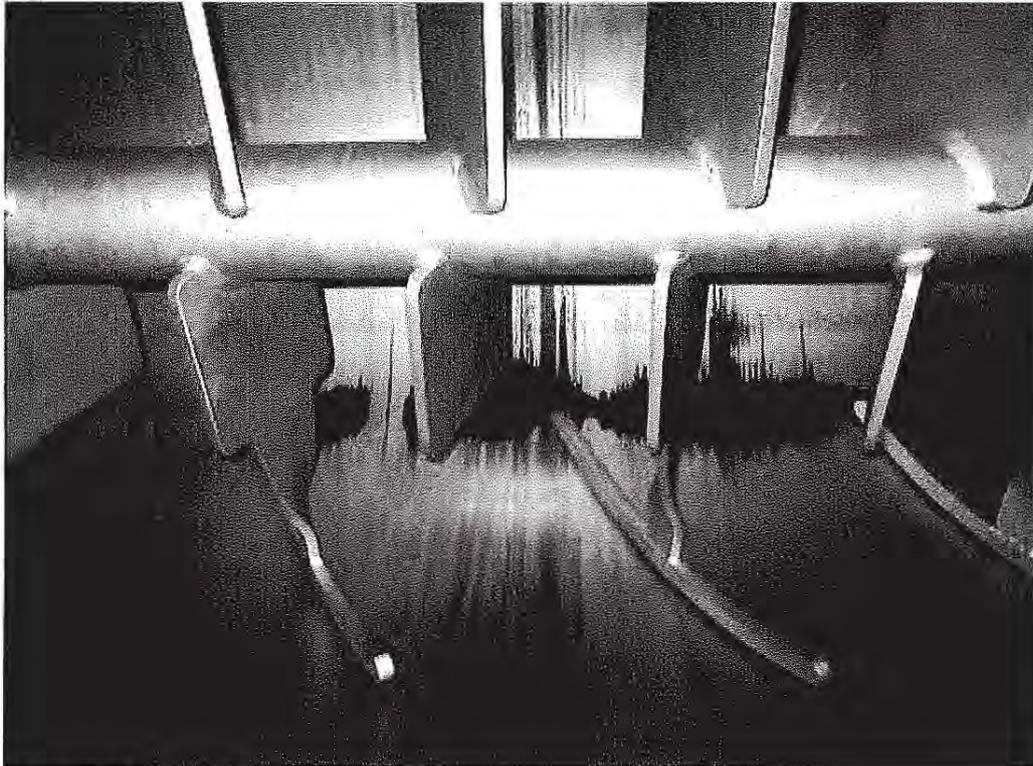
2 (4)

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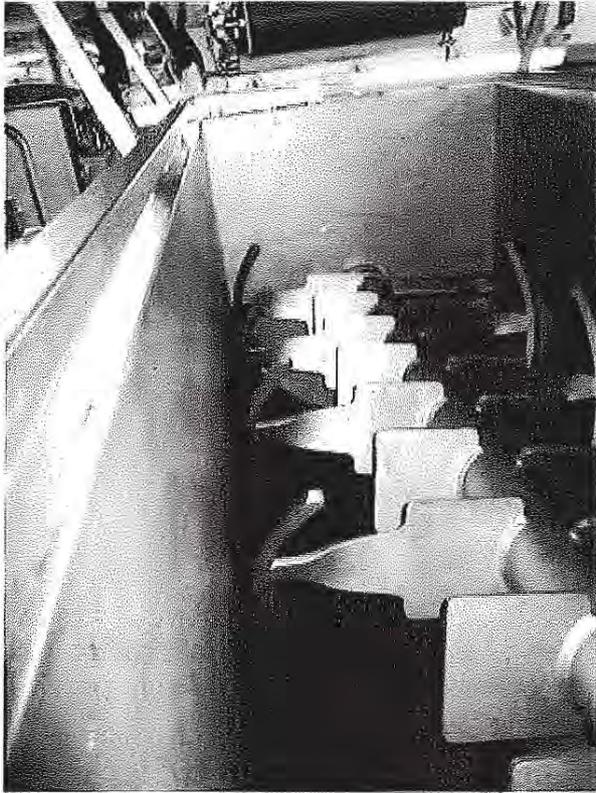
T Myllylä

2.4.2015

Fax



Picture 2. S1 blender



Picture 3. S1 blender
ATRIA SUOMI

MEMO

3 (4)

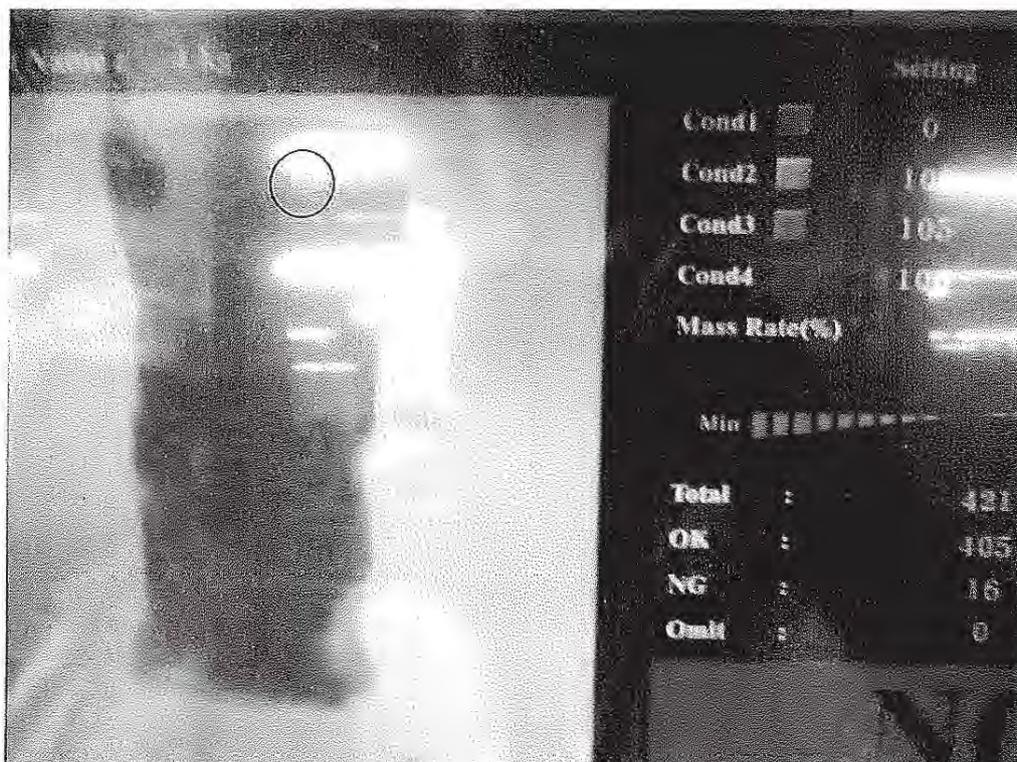
Tel. +358 40 652 5787
Fax

T Myllylä

2.4.2015

In picture 2 it can be seen that there is a gap between the flanges and the blender wall while the machine is running. A visual inspection determined that the flanges did not come into contact with the walls and no sounds were heard. Picture 3 also shows that the flanges do not touch the walls while running. A visual inspection detected no scraping of the walls by the flanges during the test and no metal residue or flakes were detected at the bottom of the device. After the audit it was discovered that the grooves were caused by the machine's breakdown in 2010. The axis managed to dislocate itself and scraped some metal off the wall of the machine.

Seven four kilogram samples of the S1 assortment were collected from Friday's 27.3. production every thirty minutes. The assortment batches were packed into a vacuum in the cutting plant and inspected by an Intellisense x-ray machine at the fresh meat facility. Before this test the functionality of the machine was established by using 1.2 mm and 2 mm test blocks. The machine detected both blocks. The test was conducted on 27.3.2015 at 13:45. Of the seven tested samples the x-ray machine rejected one package twice, but passed all the others.



Kuva 4. Röntgenin hylkäämä tuote

Picture 4. Product rejected by x-ray machine

In the above picture the x-ray machine display can be seen showing the rejected product. The device indicates where in the product the anomaly is and how big it is (the spot has been highlighted in red afterwards). The anomaly was an oblong "piece" of c. 1.5 cm x 1 cm. By feeling the product in the indicated spot no metal was discovered, so it was suspected that the anomaly was accumulated fat. The samples were inspected twice each with the cutting plant's metal detector after the x-ray test. The metal detector detected no metal in the products.

The package rejected by the fresh meat x-ray device was opened in the laboratory on 2.4. and the piece found by the x-ray was searched for by sensory means. No metals or foreign bodies were found in the product. X-ray devices can sometimes reject products due to, e.g., accumulated fat, so it is not always the case that a foreign body is necessarily responsible for the rejection.

ATRIA SUOMI

MEMO

4 (4)

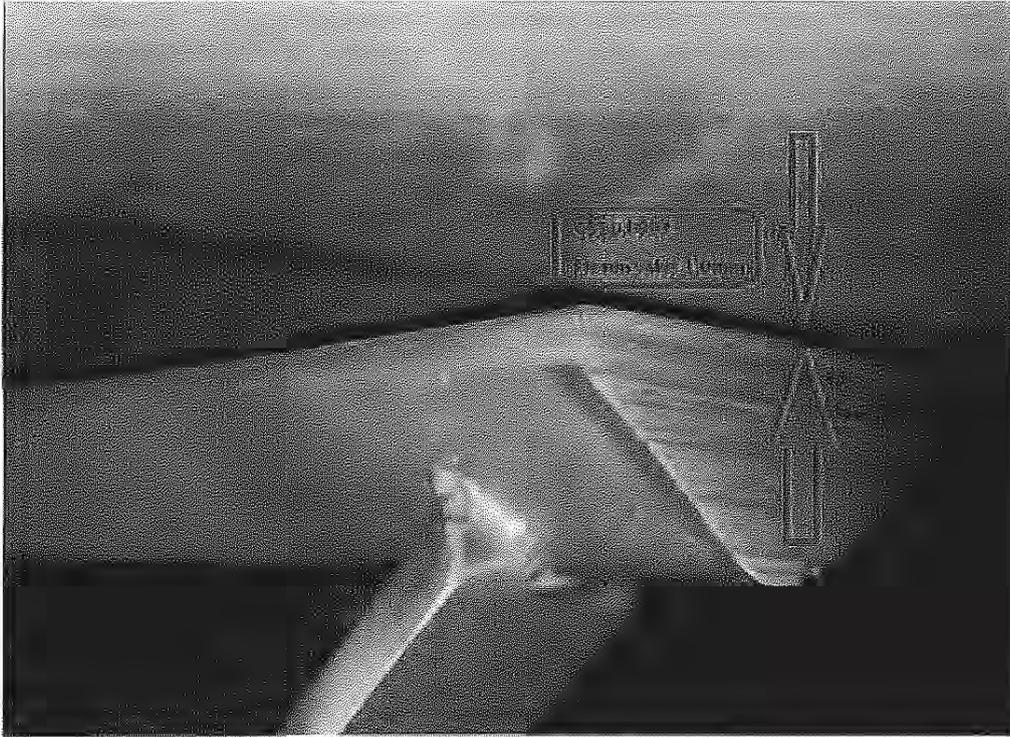
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T Myllylä

2.4.2015

Fax

A-Tekniikka measured the gap between the blender wall and axis with a feeler gauge on 2.4.2015 before starting production. According to the measurement the gap is 1 mm and there is no contact between the wall and the axis. Picture 6 demonstrates the measurement.



Picture 6. Gap width

Comments by Quality Director Seija Pihlajaviita concerning the delivery of the samples to the laboratory for investigation are as follows. "Metal dust or flakes can be so small that finding them by x-ray or a metal detector is challenging. Direct elemental analytics do not work either in detecting metal dust or flakes in food samples. Metropolilab suggested that if necessary the samples could be washed, the washing water filtered and the filter analysed by microscopy. Since this method is not exactly designed for these kinds of samples either and because the markings in the blender have appeared in 2010 it was decided that the samples would not be analysed at this stage. This method is however noted for possible future use."

ANNEXES

DISTRIBUTION

TO BE NOTIFIED

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IMPORT, EXPORT AND ORGANIC CONTROL (RALU)
Import and Export Department

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Inspection Veterinarian
Timo Laita
HKScan Finland Oy
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AUDIT REPORT

For your consideration and future procedures, The Finnish Food Safety Authority Evira dispatches the following annexed audit report, written for the audit of the supervisor of the facility approved for U.S. exports at HKScan Finland Oy's facility no. 18 in Forssa, Finland on the 9th of April 2015.

Temporary Head of Unit
Import, export and organic control

Beata Meinander

Senior Inspector
Import, export and organic control

Marianne Peltomaa

Annex Audit report Reg. no. 79/0477/2015

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Date 13.04.2015 Reg. no. 79/0477/2015

Audit of supervisor of facility approved for U.S. exports

Name of facility: HKScan Finland Oy, Forssa, Finland

Facility approval number: 18

Supervising authority: Governmental inspection veterinarian

Audit date: 9.4.2015

Auditor: Senior Inspector Marianne Peltomaa

Present at audit: Inspection Veterinarian Timo Laita
Division Manager, Senior Inspector Thimjos Ninios
Quality Manager Maarit Vähärautio
Facility Director Juha-Pekka Nieminen
Department Head Teemu Mattila
Department Head Jesse Huuhanmäki

Signature:

General

The audit in question was a NOID audit carried out after the USDA audit of 12.3.2015 to audit only the correction of grievances that resulted in the NOID (warning of revoking export rights).

OBSERVATIONS MADE DURING AUDIT

1. The carcass health marking stamping was observed for 50 carcasses. No unclear or poor health markings were observed in these carcasses. The health marking on two carcass halves was quite pale, but the facility's number was still clearly visible. The facility used hand stamping.

The facility has changed its self-monitoring since the USDA audit of 12.3.2015 that resulted in the NOID, so now the foreman inspects the quality of the health marking stamping in conjunction with HACCP monitoring. The foreman thus inspects the health markings of 5 times 15 carcasses. In addition, the initial cutting of the health markings of 10 carcasses is inspected daily. The inspection veterinarian had no remarks concerning the inspection of carcass health markings.

Facility inspectors also inspect health markings daily. A penalty payment has been set for the facility which must be paid if an inspector finds an unclear or wrongly numbered health marking. So far no unclear or incorrectly marked stamps have been detected since 12.3.2015.

2. The several damaged and worn conveyor belts detected in the cutting plant by the USDA audit of 12.3.2015 had all been replaced and were in good condition during the NOID audit of 9.4.2015. One torn conveyor belt was detected during the audit. The facility's representative ordered the belt to be changed at the end of the day. These targets have also been added to the daily operational controls by the foremen.

As a precaution the facility has specified its self-monitoring, so that the morning controller inspects the condition of conveyors, rust, peeling paint etc. daily and records these into the cleanliness inspection form. The definition of a replaceable conveyor belt has also been added to the morning inspector's instructions.

The facility has also specified the instruction "Periodic structural inspection". The instruction describes the daily and weekly inspections and procedures of structures. The inspection veterinarian had no remarks concerning this.

As a novelty, maintenance also checks the condition of conveyors and superstructures once a day during their supervision tours. Maintenance keeps records of their tours and procedures. Maintenance reports the results of their inspections briefly at the weekly meeting.

Inspectors also inspect the cutting plant conveyors more often during their own controls.

3. The superstructure, conveyor line and rail structure rust in the cutting plant detected by the 12.3.2015 USDA audit were all gone and in order during the 9.4.2015 NOID audit. Rust

prevention according to section two above. The inspection veterinarian had no remarks concerning rust or its prevention.

4. The two large holes detected in the floor of the cutting plant during the USDA audit of 12.3.2015 were repaired and in order during the NOID audit of 9.4.2015. In the future, the appearance of the hole will be prevented, according to section two. The inspection veterinarian had no remarks concerning the condition of the floor or hole prevention.
5. The canvas air duct above the open meat packing location of the packaging facility that was deemed to be dirty during the USDA audit had been replaced and was clean during the NOID audit of 9.4.2015. In the future, the appearance of dirty air ducts will be prevented according to section two. The inspection veterinarian had no remarks concerning the cleanliness of the air duct or dirtiness prevention.

Washed air bags that do not turn white were also discussed. It was agreed that if the facility has such bags investigated and can show that they are microbiologically clean they can keep using them.

6. The edge seal of the box rail opening near the CCP location was coming loose and half a piece was missing from the conveyor during the USDA audit of 12.3.2015. The seal was in order and no pieces were missing from the conveyor during the NOID audit of 9.4.2015. Preventive future measures according to section two. The inspection veterinarian had no remarks concerning these observations or future grievance prevention.
7. During the USDA audit of 12.3.2015 it was noticed that water was dripping from the ceiling of carcass warehouse 1402. The warehouse was ordered not to be used by the USDA audit until this grievance has been rectified. During the NOID audit of 9.4.2015 no more water was dripping from the ceiling of the carcass warehouse. Future preventative measures according to section two. The inspection veterinarian had no remarks concerning the correction or prevention of this grievance.
8. The plinth near the door to the refrigeration facility was broken and there was a hole in the air duct on the wall during the USDA audit of 12.3.2015. The NOID audit of 9.4.2015 discovered that the plinth had been repaired and the air duct had been fixed with duct tape pending the arrival and installation of the new ordered air duct. Future preventative measures according to section two. The inspection veterinarian had no remarks concerning the correction or prevention of this grievance.
9. The USDA audit of 12.3.2015 also discovered that the ceiling above the slaughter line was dirty at two locations. The NOID audit of 9.4.2015 discovered the slaughterhouse ceiling to be clean. In the future this grievance will be prevented by having added the low slaughter line ceiling locations to the daily washing list. The inspection veterinarian had no remarks concerning the audit observations or the facility's preventative measures.

THE FACILITY'S CONFORMITY WITH REQUIREMENTS AND FULFILLING EXPORT CONDITIONS

Evira's representative agreed with the inspection veterinarian's assessment that after the corrective measures implemented to address the grievances of the USDA audit of 12.3.2015 the facility sufficiently fulfils the requirements and export conditions set for it in terms of the inspected topics.

Evira

Control Department
Meat Inspector

9.4.2015

INSPECTION REPORT

Reference: Warning of revoking U.S. export rights, Reg. no. 668/0477/2015

Target: HKScan Finland Oy Forssa

Present: Division Head Thimjos Ninios
Senior Inspector Marianne Peltomaa
Quality Manager Maarit Vähärautio
Facility Director Juha-Pekka Nieminen
Department Head Jesse Huuhanmäki
Department Head Teemu Mattila

Inspector: Inspection Veterinarian Timo Laita

The inspection topics were the inspection of the corrective and preventive measures of the grievances detected at the facility during the USDA audit of 12.03.2015.

1. Health marking problems

The stamping of 50 pig carcasses was observed after the slaughter line's final inspection. The stamping was correctly done and even though two of the stamps were quite pale the facility's number was clearly visible. The stampings were done by hand and the automatic stamper was out of use for health markings.

The facility has changed its self-monitoring, so that the stamping quality is monitored by the foreman in conjunction with HACCP controls, i.e. the health markings of 15 carcasses every two hours are inspected daily. The health markings of 10 carcasses are also inspected in initial cutting in storage. No remarks concerning this.

2. Several worn and frayed conveyor belts in the cutting plant

The damaged and worn conveyor belts detected on 12.3. were inspected. All were now in proper condition. A belt was detected with a tear c. 2 cm long. The quality manager ordered this to be changed at the end of the day.

As a preventative measure the facility has specified its self-monitoring so that the morning inspector checks the conveyor belts, structural rust, peeling paint etc. every day. In addition, the definition of a replaceable conveyor has been added to the morning inspector's instructions. Corresponding inspection targets have also been added to the operational daily controls of the department foremen.

Evira

Control Department
Meat Inspection

9.4.2015

The facility has also specified the instruction "Periodic structural inspection". The instructions describe weekly and monthly structural inspections, conclusions and procedures.
No remarks concerning this.

3. Rusty superstructures

The grievances detected on 12.3.2015 were inspected. Everything corrected appropriately. Preventative measures as in section 2. No remarks.

4. Holes in the floor

The grievances detected on 12.3.2015 were inspected. Everything corrected appropriately. Preventative measures as in section 2. No remarks.

5. Dirty canvas air duct

The air duct had been replaced by a clean one.
Preventative measures as in section 2. Washed air ducts that still appear dirty were also discussed. If the facility can verify by, e.g., laboratory results that a duct is clean it can be used.
Currently no remarks.

6. Loose seal on the edge of the box rail opening near the CCP location and a damaged rail conveyor

Grievances addressed and target in order.
Preventative measures as in section 2. No remarks.

7. Water dripping from the ceiling of storage 1402

Storage department now dry and in order.
Preventative measures as in section 2. No remarks.

8. Storage plinth damaged and a hole in the air duct

The plinth had been repaired and repainted. The hole in the air duct temporarily fixed with duct tape. A new duct has been ordered and will be installed as soon as it arrives. This will be controlled during daily inspections. Repairs however done now to eliminate product safety hazards.
Preventative measures as in section 2. No other remarks.

9. Ceiling above slaughter line very dirty

Dirty spots have been thoroughly cleaned and ceiling is clean now.

Evira

Control Department
Meat Inspection

9.4.2015

The facility has changed the slaughterhouse cleaning program so that ceiling locations that are low and close to such activities that can send waste all the way up to the ceiling will be washed daily. No remarks concerning this.

10. The facility's conformity with requirements and fulfilling export conditions

Based on the conducted inspection the facility has corrected the grievances detected during the 12.3.2015 audit. The facility has also corrected its self-monitoring procedures so that possible grievances can be detected and corrected sooner.

Based on the inspection the facility now sufficiently fulfils the export conditions and can continue exporting pork to the U.S.

Forssa, Finland 9.4.2015

Timo Laita
Inspection Veterinarian

Annexes: The facility's self-monitoring guidelines: Operational hygiene controls
Sensory cleanliness inspections
Periodic structural inspections

Approved by
Maintained by

Maarit Vähärautio
Anniina Nummila

OPERATIONAL HYGIENE CONTROL INSTRUCTIONS

These instructions are applied daily at the HK Scan Finland Oy's Forssa facility for hygiene controls at production departments (SSOP and SPS).

SSOP

1. Product contamination

Observations; Record all observations of possible product contaminations made during the actual hygiene controls and during the day. Observations of slaughter, cutting and production hygiene. Contamination sources detected in the product itself, e.g., rail lubricant, dirt, ulcers, hairs, etc. Decision whether to act according to instructions in the case of, e.g., carcasses falling on the floor or contaminated by manure; if the decision made to act contrary to the instructions -> SSOP grievance, record observations. Attention! Clearly indicate the item / target of inspection and result of the inspection.

Corrective measures; Corrective measures are to ensure the product's appropriate end use. E.g., product cleaning, rejecting dirty parts and sending approved parts back to cutting. Or product rejection and transfer to rejected bin. Also washing of dirty lines or work surfaces.

Preventative measures; Which measures are implemented to prevent a situation from occurring again. E.g., maintenance or cleaning service work order, training, instruction, showing item causing dirt, etc.

2. Cleanliness of equipment and tools (hooks, work surfaces, devices, knives)

Observations; Surfaces in contact with product (hooks, containers, knives, conveyors, work surfaces, especially robots in the slaughterhouse) and foreign residue such as lubricant at cutting line or bursting. Product in contact or in danger of coming into contact with a contaminating surface, e.g., work surface for standing on, structures, basins.

Corrective measures; Restoring required cleanliness level; cleanup, procedures targeting the product. Cleaning of possibly contaminated products, rejecting dirty parts and ensuring appropriate further use of the product (rejection or sending approved product into cutting).

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Anniina Nummila

Preventative measures; Which measures will you implement to prevent the grievance from occurring again. Training, instruction, work order for maintenance or cleaning service. Discussion with maintenance/cleaning, showing target, replacing tools/employees, re-evaluating the SSOP program if necessary.

SPS – SOP

1. General cleanliness/hygiene

Observations; Controlling quality of cleaning service. (Also in preproduction.) All unnecessary items to be removed from production facilities. All loose items to be removed from machines and devices. All production machine parts and possible packing materials in their assigned places. If remarks concerning these record them. Rust, conveyor belt condition and observations on peeling paint. Any other issue discovered during observing that causes a hygiene risk. Inspection of dressing rooms once a month recorded here. Verification of operational intermediate washes (during product switches, machine maintenance) recorded here. Intermediate washes during product switches are verified once a week.

Corrective measures; Procedures concerning issues discovered during observation. E.g., notifying person at the workstation and cleaning workstation. Notifying maintenance about the location and severity of rust / peeling paint.

2. Condensation

Observations; Controls daily for entire department. If you detect condensation, mention where (especially if there is meat and whether the condensation has ruined the product). If no condensation is detected the controls will be recorded as complete by, e.g., "no condensation in production area".

Corrective measures; Correct handling of contaminated products (cleanup table, rejecting contaminated parts, etc.), protection, calling maintenance / cleaning service. Possible own cleanup measures.

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Anniina Nummila

3. Work practices and methods

Observations; Does a worker risk contamination due to his/her work practices. Has the workstation been so organized that there is a risk of product contamination. Comment on keeping/storage of tools and equipment. Is behaviour according to instructions. Behaviour at, e.g., cleanup station, initial cutting incoming inspection or two-knife system at the slaughterhouse.

Corrective measures; Procedures concerning issues discovered during observation. E.g., notifying workstation personnel and cleaning workstation.

4. Washing of hands

Observations; Record time interval used for observations. How many persons (approximately) went through the washing station or control space during observation. At the slaughterhouse attention is paid also to how employees wash their hands. Also comment on the washing of hands after possible blowing of the nose or touching contaminated meat (e.g., meat that fell to the floor).

Corrective measures; How many notifications were issued. As a corrective measure employees are sent back to wash their hands.

5. Clothing and headgear

Observations; Is clothing clean, does it fit well. E.g., is the hair tight inside the headgear. Possible comments on dressing rooms and storing of clothes. Concerning cotton gloves; are agreed procedures obeyed -> dirty gloves into specified bins and clean gloves are taken from specified containers instead of kept, e.g., next to workstations. Changing cotton gloves often enough. Are notified people visitors or personnel.

Corrective measures; How many people have been notified and for what. What is the extent of the problem.

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6. Passages

Observations; Do employees use passages that have been agreed upon. When coming into work, during breaks, in the canteen, at the health station, etc. Possible visitations to other departments. Movement between dirty and clean departments.

Corrective measures; How many people have been notified and for what. What is the extent of the problem.

7. Jewellery/watches/hearing protection

Observations; Following hygiene instructions recorded especially in terms of wearing jewellery and watches. Are notified persons, visitors or own personnel. Comments about the cleanliness of hearing protection and whether agreed procedures are obeyed (see instruction 2.1, Cleaning program).

Corrective measures; How many people were notified and for what. What is the extent of the problem. Possible removal of jewellery, cleaning of hearing protection, etc.

General

The SSOP targets in the form, condensation and General cleanliness are to be observed and recorded daily. Other SPS targets are to be observed and recorded so that all items are covered during the week. For the SSOP observations the targets observed/recorded daily are specified, and it must be ensured that the entire department is covered during the week. Time of day must also be recorded in the observation column. All grievances must however be dealt with immediately!

Each SPS-SOP target can be elevated to an SSOP target if product safety has been compromised due to negligence. Should this happen the last column of the SPS-SOP target is checked and standard procedures for SSOP targets will be implemented.

The person conducting the hygiene controls must react to and record all procedures if grievances keep recurring over a longer period of time despite preventative and corrective measures. Quality correspondent responsible for re-evaluating the SSOP program must be notified.

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Anniina Nummila

Definition of a replaceable conveyor

A conveyor must be replaced immediately (prevented from being used) if there is a risk that foreign bodies come loose from the conveyor and the conveyor causes a product safety risk. If the conveyor belt's surface is worn where it comes into contact with the product, but nothing comes loose it can be replaced after production. Damaged edge strips can be trimmed without replacing the belt; this can also be scheduled for, e.g., the following weekend.

Time of day; to be recorded

Schedule

The schedule for SSOP target preventative measures recorded in the column

Responsible person;

Observer

SENSORY CLEANLINESS INSPECTION, cleanliness inspector instructions

The form is filled out in accordance with the cleaning program on the morning following the cleaning before production is started.

Signing: the cleanliness inspector signs the inspection as complete and enters the date and time of the inspection.

Target: All surfaces in contact with the product are in **bold (SSOP)**.
The inspector signs the observation result in the column next to the inspected target (P)
0 -> the inspected machine, device or structure is clean.

Target in contact with food stuff (SSOP):

2, if dirty -> production will not start until the target has been washed.

If the uncleanliness is in the structure of a device that comes into contact with the product, which itself, however, does not come into contact with the product, a 1 can be entered if no immediate cleaning is required before production starts. In this case "structure" must be entered after the device and a more detailed description of the uncleanliness at the bottom of the form.

Target not in contact with food stuff (SPS-SOP):

1, if only slightly dirty -> will be washed during next cleaning.

(A 2 can be entered if the target is recurring and has not been washed or scheduled for washing)

2, if dirty enough to require washing before production (e.g., pieces of meat).

Corrective measures (K);

1 = washed immediately, 2 = washed by cleaning company, 3 = to be washed at next cleaning

Signing and clocking corrective measures;

The cleanliness inspector records the code of the correction and the person who implements the correction signs them as complete and enters the time.

Cleanliness inspector's corrective measures and observations;

Number code for location and possible type (meat, fat, etc.) of dirt recorded. Implemented corrections and other possible observations recorded. *Other possible observations include structural and conveyor-related shortcomings such as: damaged conveyors, rust, peeling paint, damaged floor. These will also be always reported to department foreman and/or maintenance who initiate corrections.*

The facility has inspected corrective measures;

The facility's representative must inspect the corrections implemented by the cleaning service immediately after the cleaning if the surfaces coming into contact with the product are dirty. **(Production will not start until these surfaces are clean and inspected.)** Signature, date and time after inspection.

Other targets will be inspected during the following inspection.

Preventative measures;

Targets in contact with food stuff (SSOP) always require preventative measures as well. Such measures include, e.g., incorporating the cleaning service representative in the morning inspection, discussing targets, replacing tools/detergents, training/instruction, better compliance with the program. If a mistake is recurring, the quality manager responsible for re-evaluating the SSOP program is notified.

Glass and plexiglass

Glass and plexiglass are inspected specific to each line. The facility's representative inspects daily the integrity of the glasses (windows, mirrors) and other fragmenting items (e.g., plexiglass) used in production. The column K is marked with 0 if everything is in order. If there are remarks or need for corrections, the column is marked with 1 and the section "cleanliness inspectors' observations" records where the broken glass is and any other possible comments. Shortcomings are to be reported to the foreman who contacts maintenance.

Deviations

Deviation reports are always filed if the form is marked with a 2.

Condensation

The column condensation is marked with 0 if there is no condensation in the device or structure, and with 1 if there is condensation in the device or structure.

Attention! Condensation water requires corrections too, if it occurs. Always mention if there is produce underneath and if it is at risk of contamination.

HK SCAN FINLAND OY Forssa	9.11.2004 (orig.) 27.3.2015 (v6)	SELF-MONITORING
	Approved by	Maarit Vähärautio
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PERIODIC INSPECTION OF STRUCTURES

PURPOSE

This instruction describes the inspection of structures incorporated in the self-monitoring.

PROCEDURE

The condition of structures is inspected *weekly* and during a monthly tour.

The weekly inspection is a part of the maintenance program and the responsibility for its implementation is at maintenance. The monthly controls verify the functionality of the maintenance program. The monthly controls are implemented together with the cleaning service's morning tours. Each department will be inspected 4 times p/a. The controls pay attention to, e.g., structural integrity, conveyor condition, lighting output and condition, integrity of lamp protective covers, possible dripping condensation, air pressures and surface hygiene, occurrence of rust, condition of glass/plexiglass. Special attention is paid to product contact surfaces and structures above the produce. The monthly tour also pays attention to general cleanliness and tidiness. In addition, the tour, conducts a risk analysis of observed shortcomings. Conveyors must be changed immediately (prevented from being used) if there is a risk that foreign bodies come loose from the conveyor and the conveyor causes a product safety risk. If the conveyor belt's surface is worn where it comes into contact with the product, but nothing comes loose it can be replaced after production. Damaged edge strips can be trimmed without replacing the belt; this can also be scheduled for, e.g., the following weekend.

Reports are written for the tours. A correction plan will be made for observed shortcomings. The plan contains a schedule and each item will be assigned an SAP number for checking the situation.

The results and corrective measures and schedules of weekly inspections are reviewed by maintenance at each department's weekly meeting. The inspection of procedures agreed upon during the monthly tours takes place during the next tour.

The Quality Manager, supervising authority and representatives of maintenance and production attend the tour.

RESPONSIBILITIES

The Quality Manager is responsible for carrying out the tours in accordance with instructions. Maintenance is responsible for fixing any shortcomings or faults observed during the tours.

Annex VIII is not published.