United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

DEC 0 7 2009

Eeva-Riitta Wirta
Evira
Mustialankatu 3
FI-00790 Helsinki, Finland

Dear Dr. Eeva-Riitta :

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Finland's meat inspection system July 29 to August 12, 2009. Comments received from the government of Finland have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

for Manzoor H Chaudhry
James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

Steve Huete, Counselor, US Embassy, The Hague, Netherlands
Bernard Van Goethem, Director, Directorate E, European Commission, Brussels
Canice Nolan, First Secretary, EU Mission to the US, Washington, DC
Debra Henke, Minister-Counselor, US Mission to the EU, Brussels
Ghislain Marechal, EC - DG SANCO - International questions (bilateral)"
David Young, FAS Area Director
FAS/OSTA
Ann Ryan, State Department
Alfred Almanza, Administrator, FSIS (Mila Cook gets e-mail)
Lisa Wallenda Picard, Chief of Staff, OA
Ronald Jones, Assistant Administrator, OIA
James Adams, Director, IAS, OIA
Andreas Keller, Director, IES, OIA
Rick Harris, Director, IEPS, OIA
Yolande Mitchell, IES, OIA
Jerry Elliott, Director, IID, OIA
Phil Derfler, FSIS, OPPD
Dan Engeljohn, FSIS, OPPD
Clark Danford, Director, IPD, OPPD
Stephen Hawkins, Acting Director FSIS Codex Programs Staff, OIA
Faiz Agarib, IES, OIA
Country File

FSIS:OIA:IAS:James Adams:202-690-0997:Final Report Letter-Finland [FY2009]:11-30-2009

FINAL REPORT OF AN AUDIT CARRIED OUT IN FINLAND COVERING FINLAND'S MEAT INSPECTION SYSTEM

JULY 29 THROUGH AUGUST 12, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. SUMMARY
   1.1 Description/Eligibility
   1.2 Comparison of Current Audit and Previous Audit
   1.3 Summary Comments for the Current Audit

2. INTRODUCTION

3. OBJECTIVE OF THE AUDIT

4. PROTOCOL

5. LEGAL BASIS FOR THE AUDIT

6. SUMMARY OF PREVIOUS AUDITS

7. MAIN FINDINGS
   7.1 Legislation
   7.2 Government Oversight
   7.3 Headquarters Audit

8. ESTABLISHMENT AUDITS

9. LABORATORY AUDITS

10. SANITATION CONTROLS
   10.1 SanitationStandard Operating Procedures
   10.2 Sanitation Performance Standards
   10.3 EC Directive 64/433

11. ANIMAL DISEASE CONTROLS

12. SLAUGHTER/PROCESSING CONTROLS
   12.1 Anti-mortem/Postmortem Inspection Procedures
   12.2 Humane Handling and Slaughter
   12.3 HACCP Implementation
   12.4 Testing for Generic *Escherichia coli*
   12.5 Testing for *Listeria monocytogenes*
   12.6 EC Directive 64/433

13. RESIDUE CONTROLS
   13.1 EC Directive 96/22
   13.2 EC Directive 96/23

14. ENFORCEMENT CONTROLS
   14.1 Daily Inspection

14.2 Testing for *Salmonella*
14.3 Species Verification
14.4 Monthly Reviews
14.5 Inspection System Controls

14. EXIT MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [Finnish Food Safety Authority (FSA)]
DDG	Deputy Director General
Evira	Elintarviketurvallisuuvirasto
E. coli	*Escherichia coli*
EC	European Commission
FINAS	Finnish Accrediting Service
FSA	Food Safety Authority
FSIS	Food Safety and Inspection Service
MIU	Meat Inspection Unit
NFA	National Food Agency
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SO	Senior Officer
SSOP	Sanitation Standard Operating Procedures
U.S.	United States
VEA	European Community/United States Veterinary Equivalence Agreement

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Finland from July 29 through August 12, 2009. This was a routine audit with a special emphasis on microbiological testing programs and corrective actions taken in response to non-compliance identified during the previous audit. Finland is eligible to export red meat and red meat products to the United States. Between January 1 and July 31, 2009, Finland exported 8,686,377 pounds of meat products to the United States, of which 3,670,054 pounds were reinspected at US ports of entry (POE). A total of 3,428 pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during May 2008 resulted in no restrictions of the ability of any establishment in Finland to export meat products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		07/29-08/12, 2009	05/14-05/29, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Establishment Level	3	4
Laboratories Audited			
	Microbiology	1	1
	Residue	0	1
Establishments Audited			
	Slaughter/processing	3	3
	ID Warehouses	0	1
Enforcement Actions Initiated			
	NOID	2	0
	Delistment	0	0
Risk Area Findings		(3 Ests. audited)	(4 Ests. audited)
	Sanitation Controls (SSOPS, SPS)	9	10
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	3	1
	Humane Handling and Slaughter	2	0
	Residue Controls	0	0
	Microbiology Controls	6	1
	Inspection/Enforcement Controls	3	1

1.3 Summary Comments for the Current Audit

Two of the three slaughter/processing establishments received Notice Of Intent to Delist (NOID) during the current audit for inadequate implementation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS) requirements. The results of this audit raised serious concerns in virtually all the risk areas except for animal disease and residue controls.

During this audit, it was found that monthly supervisory reviews of certified establishments were being performed and documented as required. However, it was also noted upon the review of the last twelve monthly supervisory reports that the Central Competent Authority (CCA) audits did not adequately identify/correct requirements with pre-operational SSOP and Hazard Aanalysis Critical Control Point (HACCP). The review of the supervisory reports also indicated that the audits did not adequately identify/correct European Union (EU) and Food Safety Inspection System (FSIS) requirements in the risk areas related to sanitary operation, light, ventilation, ante-mortem and humane handling in all certified establishments.

2. INTRODUCTION

The audit was conducted in Finland from July 29 through August 12, 2009.

An entrance meeting was held on July 29, 2009, in Helsinki with the CCA. At this meeting, the auditor confirmed the objective and scope of the audit, auditor's itinerary, and requested additional information necessary to complete the audit of Finland's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Finnish Food Safety Authority (FSA).

2. OBJECTIVE OF THE AUDIT

The objectives were (1) to determine whether the concerns identified during the May 2008 audit had been appropriately addressed and (2) to evaluate the performance of the FSA with respect to government oversight, enforcement of the FSIS regulatory requirements and requirements stipulated in EC Directives relative to maintaining an inspection system equivalent to that of the United States. This included the following areas of special emphasis:

- Pathogen Reduction (PR)/HACCP requirements
- Humane handling and slaughter of livestock
- Government oversight
- Daily inspection
- Payment of inspectors
- The CCA's oversight of slaughter establishments' implementation of controls to prevent contamination of carcasses with feces, ingesta, or milk
- Field inspection personnel's knowledge and application of the FSIS regulatory requirements

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection head quarters. The third part involved on-site visits to three swine slaughter/ processing establishments. The fourth part involved visit to a private microbiology laboratory conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella.*

Program effectiveness determinations of Finland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of SSOP, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls including a testing program for *Salmonella.* Finland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by Finland and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the entrance meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission (EC) Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS's requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella.*

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Finland under provisions of the Sanitary/Phytosanitary Agreement. Alternate procedures that have been recognized as equivalent: Finland may allow either establishment or government employees, who are fully trained, to take samples applicable to generic *E. coli* and *Salmonella* testing programs and an equivalence determination allowing the use of an alternate laboratory testing method ISO 6579:2002(modified) for *Salmonella.* In addition, FSIS has granted Finland an equivalence determination allowing the use of methods NMKL 147:1993 for generic *E. coli* and NMKL 144, 3rd ed. 2005 for *Enteriobacteriacae.*

4. LEGAL BASIS FOR THE AUDIT

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 Federal Meat Inspection Regulations (9 CFR Parts 301 to End), which include the Pathogen Reduction/HACCP regulations

In addition, compliance with the following European Commission Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of ß-agonists"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following non-compliances were reported during the FSIS audit of Finland's meat inspection system conducted in May 2008:

- No establishment was delisted or received a NOID by the CCA
- In one of the three slaughter/processing establishments audited, the ongoing SSOP requirements were not met
- In two of the four establishments, the SPS requirements were not met.
- Some EC Directive requirements were not adequately enforced in two of the four certified establishments audited.
- The Government inspector was not observing and palpating the mesenteric lymph nodes at the swine post-mortem inspection station as required by US and European Commission regulations.
- In one of the three slaughter/processing establishments audited, some of the HACCP requirements were not met.
- Deficiencies regarding testing for generic *E. coli* were reported in all three establishments.
- In the microbiology laboratory rusty baskets in the cabinets and rusty hooks attached to the wall, for the storage of small laboratory utensils were observed.

The following deficiencies were reported during the FSIS audit of Finland's meat inspection system conducted in May 2007:

- In one establishment, viscera trays in the evisceration room were observed with buildups of organic material.

- Non-compliances regarding enforcement of some aspects of FSIS regulatory requirements were reported in the two establishments audited.
- Sanitation non-compliances were reported in both establishments.
- In one of the two establishments audited, government inspectors were not palpating the pork tongues at the post-mortem inspection station as required by European Commission regulations.
- Non-compliances regarding HACCP programs were reported in one of the two establishments audited.

In two establishments audited, the provisions of EC Directive 64/433 were not effectively implemented. The following non-compliances were observed:

- In one establishment, white working clothes and street clothes were hanging together in an employee locker room, causing insanitary conditions.
- In one establishment, viscera trays in the evisceration room were observed with buildup of organic material.
- In one establishment, a metal piece welded to the pork belly belt in the cutting room had uneven and rough welding, creating a potential source of contamination.

One private laboratory located in establishment 18 was audited; the following deficiency was observed:

- The year in which samples were received had not been recorded in the sample-receiving log book.

These specific non-compliances were found to have been corrected by the May 2008 FSIS audit.

6. MAIN FINDINGS

6.1 Legislation

The food safety authority, Elintarviketurvallisuusvirasto (Evira) has updated guidelines relating to HACCP, SSOP and other inspection requirements, for example, FSIS Directive 6420.2 (Verification procedure for controlling fecal material, ingesta and milk in slaughter plants). All relevant EC Directives are incorporated in Finnish legislation.

6.2 Government Oversight

In order to improve the control and supervision of activities of the field inspectors, the National Food Agency (NFA) was reorganized in September 2005, and its headquarters staff is now directly supervising government veterinarians assigned to the establishments certified for export to the United States. The NFA has become part of the FSA since May 2006. The provincial veterinarians, who are part of the Ministry of Interior (not part of the NFA and Ministry of Agriculture and Forestry) have been removed from their inspection responsibilities and are no longer involved in providing oversight in establishments certified for export to the United States.

The NFA and other staffs and some functions of the Department of Food and Health of the Ministry of Agriculture and Forestry have been merged into the FSA, since May 2006. The followings were the previous departments, since May 2006.

1. Department of Agricultural Production Control
2. Department of Food and Veterinary Control
3. Department of Animal Diseases and Food Safety Research
4. Department of Administrative Services

The FSA has a new organization and the above departments have now been restructured into three new departments, since January 1, 2008. The followings are the new departments:

1. Administrative Department
2. Control Department
3. Research Department

All these new departments are sectioned in to several units.

The new Meat Inspection Unit (MIU) is responsible for meat inspection and supervision at U.S. certified establishments. MIU is functioning directly under the supervision of Deputy Director General (DDG) of FSA.

6.2.1 CCA Control Systems

The FSA has been reorganized since January 1, 2008. There are three new departments under the direction of Director General as follows:

1. Administrative Department
2. Control Department
3. Research Department

The meat inspection personnel have become the part of new MIU, which is directly under the supervision of DDG.

Mainland Finland is divided into five provinces. Two of the four establishments certified for U.S. export are located in the province of Western Finland and the other two in the province of Southern Finland.

6.2.2 Ultimate Control and Supervision

The tasks of the current FSA office includes meat inspection in slaughterhouses and other establishments, approval of the slaughterhouses and other establishments, national testing programs for residues and for *Salmonella* in meat, and controls for meat exports outside the EU. The in-plant inspection personnel are now supervised by the FSA Senior Officers stationed (SO) at the FSA Headquarters in Helsinki.

Since September 2005, a SO from Helsinki has started performing monthly internal audits (reviews) of the establishments certified as eligible to export products to the U.S. These monthly supervisory reviews now provide evaluation of inspection personnel and the SO is responsible for ensuring that establishment officials take appropriate corrective actions in response to identified non-compliances. This SO has been given authority to verify that corrective actions have been taken by establishment officials.

Nationally developed inspection forms are in use in all establishments for supervision of establishment compliance. The guidelines of written instructions for supervision of establishments eligible for U.S. export, including evaluating PR/HACCP programs and compliance with other FSIS requirements have been updated.

6.2.3 Assignment of Competent, Qualified Inspectors

In Finland, veterinarians take courses in meat inspection in the curriculum of their formal education. After graduation, veterinary graduates are immediately eligible to work in slaughterhouses, as they have already completed a practical training period in a slaughterhouse and passed the post training examination, as part of the curriculum. However, an extra four weeks of practical training in a slaughterhouse and a completion of a specific post training test are considered an advantage, when a veterinarian wishes to pursue a career in meat inspection in a slaughterhouse.

Non-veterinary "auxiliaries" are required to take 200 hours of practical training on the slaughter line and 400 hours of theoretical class work, after which they must also pass specific examinations before being qualified to work in export meat establishments. Short term absences within the auxiliary staff in a certified establishment are often filled from the establishment's trained staff, however, once engaged to work as an auxiliary; these plants provided employees are paid by the FSA for the work performed.

The FSA organizes a two-day training courses for official veterinarians twice a year. Similar two-day training courses for auxiliaries are offered in spring and autumn.

In November 2007, a one-day training course was organized and presented by the FSA to provide additional training on U.S. export issues including HACCP, SSOP and SPS requirements to both inspection personnel and establishment personnel. A similar one day training course was also organized for both inspection and establishment personnel in November 2008.

In November 2007, a two-day training course was organized by the FSA to provide additional training in various subjects, such as animal diseases and animal welfare to official veterinarians in slaughter houses.

In March 2008, a two-day training course was organized by the FSA to provide training to auxiliaries in slaughter houses regarding the new organization of FSA, meat inspection, residues, and animal diseases.

In April 2008, a two-day training course was organized by the FSA to provide training to officials veterinarians in slaughter houses regarding the new organization of FSA, meat inspection, transportation, and matters related to maintaining the ability to work.

Keeping with the training schedule mentioned above, the FSA conducted trainings in October and October/November 2008 for official veterinarians and auxiliaries respectively. The training course material for the veterinarians included animal disease preparedness plans for slaughter houses, decision making in a meat inspection system, EU animal welfare inspections during transport, and various group exercises. The auxiliaries' training included post mortem examinations of various animal species, animal diseases, and occupational health and wellbeing issues.

In March 2009, the FSA organized training for official veterinarians on topics including animal diseases, animal welfare and inspection of animal transportation. In February/March 2009 the FSA organized training for the auxillaries on the topics including animal diseases, animal welfare, issues on meat inspection audits and contingency plan for animal diseases handling in slaughterhouse.

6.2.4 Authority and Responsibility to Enforce the Laws

The FSA has the authority for carrying out Finland's meat inspection program, including oversight and enforcement of FSIS regulatory requirements in establishments certified to export to the United States. The FSA not only has the authority to certify establishments for export to the United States, but also has the responsibility for withdrawing such certification when establishments do not meet FSIS requirements.

6.2.5 Adequate Administrative and Technical Support

The FSA has adequate administrative and technical support to operate Finland's meat inspection system, and has the resources and ability to support a third-party audit.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters and in-plant inspection offices at the audited establishments.

The records reviews also focused on food safety hazards and included the following:

- Internal review reports/Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors
- Animal disease status
- New laws and implementation documents such as regulations, notices, directives, and guidelines
- Official communications with field personnel, both in-plant and supervisory, in U.S. certified establishments
- Sampling and laboratory analyses for residues
- Sanitation, and slaughter inspection procedures and standards

- Species verification policy
- Enforcement actions

No concerns arose as a result of the examination of these documents.

6.3.1 Audits of Local Inspection Sites

The FSIS auditor reviewed Finland's meat inspection records maintained in three establishments certified to produce and/or export meat to the United States. In addition, the auditor interviewed the veterinarian-in-charge at each establishment.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor audited visited three slaughter/processing establishments. None of the establishments were delisted by Finland's Inspection Service as a result of failure to meet FSIS and EC requirements. Two of the three establishments audited received a NOID from Finland's Inspection Service.

8. LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

No residue laboratory was included in the scope of this audit.

Microbiology laboratory audits focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs. In private laboratories used to test United States samples, the auditors evaluate compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements. The following observation was made as a result of the laboratory's audit:

- The CCA does not directly audit or oversee the private laboratories analyzing microbiological samples for the certified establishments, but relies on the audits conducted by FINAS, a national accreditation body.

The following laboratory was audited:

The private microbiology laboratory "HK RUOKATALO OY" is housed within the premises of establishment 18 in Forssa. This laboratory, in addition to establishment 18, conducts *Salmonella* and generic *E. coli* testing of porcine carcasses for establishment 85 in Mellila.

The following concerns arose as a result of the laboratory's audit:

- The electronic record for the receipt of samples did not capture the times of receipts of samples.
- The time and temperature for two refrigerators used to store samples and reagents were not being monitored as required by the laboratory's quality control program.
- The sterilizing autoclave's monitoring chart that is used to document the incubator's default temperature setting once a day, did not record the time and temperature in accordance with the laboratory quality control program. The calibration of the incubator was not included in the quality control program. The record which was used to document the time/temperature of the duration of incubation for sterilization of laboratory glassware and small tools was not available for the auditor's review.
- The qualitative test to check the level of sterilization utilized colorimetric vials which change color to indicate the level of sterilization in the incubator's interior. The vials being used were expired and the results were not being matched against any established standard.

9. SANITATION CONTROLS

As stated previously, an FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of the establishments, except as noted below, Finland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

In addition, Finland's inspection system had controls in place for water potability, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

Specific noncompliances are noted on the attached individual establishment reports.

9.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met. The SSOPs in all of the three establishments audited were found to meet the basic FSIS regulatory requirements; however, the review of each establishment's and local inspection's SSOP records for 60 -90 days, in some cases even longer, did not reveal similar findings as identified below during the audit.

The review of the establishment's sixty days preoperational records, including the record for the day of the audit, did not identify problems with the implementation of pre-operational procedures concerning employees' hand tools or sanitizers. The review of local inspection staff record for the last 60 days, including the day of the audit, and the review of last twelve

monthly supervisory reports did not indicate problems with the implementation of pre-operational sanitation procedures concerning employees' hand tools or sanitizers.

9.2 Sanitation Performance Standards

The review of each establishment's and local inspection's Standard Operating Procedure records for 60 -90 days, in some cases even longer, did not reveal the non-compliances identified below during the audit:

- In one of the three establishments audited, SPS requirements pertinent to lighting were not met.
- In two of the three establishments audited, the SPS requirements regarding ventilation were not met.
- In all establishments, the SPS requirements for sanitary operations were not met.

See the attached individual establishment reports for a list of non-compliances.

9.3 EC Directive 64/433

In all certified establishments audited, some EC Directive requirements were not adequately enforced.

Summary of non-compliance observed at individual establishments:

Non-compliance with the requirements of sanitary operation were found in all three establishments audited and summarized below.

- In one establishment: a) While conducting the pre-operational verification several hoisting hooks on the slaughter line were observed to be covered with a massive amount of pig hair. b) While conducting the pre-operational verification the tufts of hair found enmeshed around the shaft, chain and other parts of the de-hairer machine.
- In one establishment: a) During the handling of meat affected with an abscess, an employee, after handling a water hose, proceeded to handle meat without changing his gloves which was not consistent with the establishment's standard operating procedures and could result in product contamination b) Rolls of clear plastic used for shipping product was stored on the loading dock. Another such roll covered in dirt was left unattended between a post and the wall near packing room. The rolls could potentially be used in the handling and packaging of edible products and could, therefore, potentially contaminate/adulterate product. c) A barrel of an unidentified chemical was stored in the shipping area; the contents, therein, could be misused resulting in contamination of the product. d) In a processing room, edible containers were stored on top of a chemical tank without a lid. The containers were exposed to chemicals and therefore may indirectly contaminate the product.
- In one establishment: a) The steam cabinets for scalding pigs had a thick layer of grime build up in their interiors and was creating insanitary conditions. This observation was not identified in any of the maintenance programs records maintained at the establishment.
  b) In the chemical storage room located near the swine hoist line, rusty shelves were littered with miscellaneous articles were creating insanitary conditions and potential for

product contamination. In an adjacent room, a chemical barrel of motor oil was stored directly on the floor creating insanitary conditions and the potential for product contamination during the handling or spillage of the chemical.

Non-compliance with the requirements for ventilation was found in two of the three establishments audited and summarized below.

- In one establishment: a) The overhead structure in a carcass cooler had beaded condensate above the exposed carcasses. Although, no direct product adulteration was observed at the time of audit, condensate could potentially contaminate the carcasses stored under the affected area. A similar finding was noted during the previous audit of this establishment. Review of 90 days of the establishment's SSOP and SOP documents did not identify any trend related to the finding. Except for sporadic citing of condensate in the documents, there were no distinct concerns on the issue b) In the MDM room, over head exhaust conduits were corroded at two different locations resulting in holes with avulsing rusty content in close proximity to tanks containing edible product. The corroded material from the overhead exhaust could potentially contaminate nearby product. In the same room a pipe connecting to a cooling condenser was leaking; the leakage was dripping onto utensils and containers for edible product. The containers were loosely covered with a plastic sheet. The affected scoops could have been utilized in handling the edible product because similar scoops are used plant-wide.
- In one establishment: Beaded condensate was observed on the overhead structures above the exposed product at more than three locations within the processing room as well as on the carcass rail exiting a cooler. The product stored under the affected area was potentially exposed to contamination from the condensate. The review of the establishment's and local inspection's daily records did not indicate condensation to be a problem.

Non-compliance with the requirement for lights was found in one of the three establishments audited and summarized below.

- In one establishment: All light fixtures over the swine finish line were dirty, cracked, and had several dead flies stuck to their inner surfaces creating insanitary operational conditions and posing potential for product contamination. This issue was not addressed in any of the establishment's maintenance records. The establishment replaced all light fixtures with new ones. The review of the establishment's pest management program indicated the entry of flies in a different part of the facility despite the use of ultra-violet traps.

Non-compliances with the requirements for humane handling were found in two of three establishments audited and summarized below.

- In one establishment: Protruding bolts on a restraining steel gate were observed at the unloading dock. The bolts were posing potential for injuries to pigs during the unloading process. Neither the local inspection staff records nor the CCA's supervisory reviews addressed the presence of the protruding bolts on the restraining steel gate. The CCA should have identified/corrected the findings which local inspection staff failed to identify/correct in the first place. The establishment gave assurances that the bolts would be filed and evened with the gate.
- In one establishment: The provisions of Finnish Animal Welfare Degree (396/1996) were not met. In the absence of feeders it could not be determined how the pigs that were kept

more than 12 hours or over the weekend in the establishment were fed as required under the aforementioned provisions.

Non-compliance with the requirement for ante-mortem inspection was found in one of three establishments audited and summarized below.

- In one establishment: The review of more than six months worth of ante-mortem records maintained at the local inspection office revealed that a thermometer was not utilized during ante-mortem inspection. The lack of thermometer use allows for swine running a temperature of 106 °F or more proceeding for slaughter. FSIS regulation requires any swine having a temperature of 106°F or higher shall be identified and condemned on ante-mortem b) A swine reported of having received ante-mortem inspection but suspected of being sick was stunned, stuck, and bled outside the stunning area. Blood spilled onto the floor can collect within the boots of employees and thus spread to live animals in the pens.

All non-compliances noted above were either immediately corrected or assurance was given by the local inspection staff to have the findings corrected as soon as possible.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Finland's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem dispositions; humane handling and slaughter; post-mortem inspection procedures and disposition; ingredients identification; control of restricted ingredients, formulations, processing schedules, equipment, and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Ante-mortem /Post mortem Inspection Procedures

The review of more than six months worth of ante-mortem records maintained at the local inspection office revealed that a thermometer was not utilized during ante-mortem inspection. The lack of thermometer use allows for swine running a temperature of 106 °F or more proceeding for slaughter. FSIS regulation requires any swine having a temperature of 106°F or higher shall be identified and condemned on ante-mortem.

11.2 Humane Handling and Humane Slaughter

Although the review of local inspection records or the supervisory reviews did not identify any concerns with the humane handling of the livestock, the following concerns arose as a result of humane handling and humane slaughter verification:

- In one establishment: The provisions of Finnish Animal Welfare Degree (396/1996) were not met. In the absence of feeders it could not be determined how the pigs that were kept more than 12 hours or over the weekend in the establishment were fed as required under the aforementioned provisions.
- In another establishment protruding bolts on a restraining steel gate were observed at the unloading dock. The bolts were posing potential for injuries to pigs during the unloading process. Neither the local inspection staff record nor the CCA's supervisory reviews addressed the presence of the protruding bolts on the restraining steel gate. The CCA should have identified/corrected the findings which local inspection staff failed to identify/correct in first place.

11.3 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to FSIS regulatory requirements.

The HACCP programs were reviewed during the on-site audits of all three establishments.

In two of the three slaughter/processing establishments audited, the following basic HACCP requirements were not met:

- In one establishment, the step for offline slaughter of suspects (sick) pigs was neither shown on the flow diagram nor was a hazard analysis conducted.
- In one establishment, the hazard associated with the rework step was neither on the flow diagram nor was a hazard analysis conducted.
- In one establishment, the hazard analysis for the ear removal/stamping step had not been conducted as was shown in the flow diagram.

11.4 Testing for Generic *E. coli*

Finland has adopted the FSIS regulatory requirements for testing for generic *E. coli* with the exception of the following equivalent measure(s):

- Finland may allow either establishment or government employees, who are fully trained, to take samples applicable to generic *E. coli* testing program.
- In lieu of generic *E. coli* testing of raw product, Finland can test raw product for *Enteriobacteriaceae* and Total Viable Count.

The establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli.*

No concern arose.

11.5 Testing for *Listeria monocytogenes*

None of the three establishments audited were producing ready-to-eat products for export to the United States. Accordingly, FSIS requirements for testing for *Listeria monocytogenes* did not apply.

11.6 EC Directive 64/433

No concern arose. The deficiency identified during the previous audit was verified to be corrected.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Finland's residue testing program was evaluated at the establishment level. No deficiencies were reported. The National Residue Testing Plan for 2009 was on schedule.

No residue lab was within the scope of this audit.

12.1 EC Directive 96/22

According to the audit conducted in May 2008, the provisions of EC Directive 96/22 in the government residue laboratory "Research Department Chemistry and Toxicology" were effectively implemented. No residue lab was audited during the current audit.

12.2 EC Directive 96/23

According to the audit conducted in May 2008, the provisions of EC Directive 96/23 in the government residue laboratory "Research Department Chemistry and Toxicology" were effectively implemented. No residue lab was audited during the current audit.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella.*

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the establishments audited.

13.2 Testing for *Salmonella*

Finland has adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

- FSIS has granted Finland an equivalence determination allowing the use of an alternate laboratory testing method for *Salmonella* (ISO 6579:2002(modified).
- Finland may allow either establishment or government employees, who are fully trained, to take samples applicable to *Salmonella* testing program.

All three establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to FSIS regulatory requirements. *Salmonella* testing was properly conducted in the slaughter establishments audited.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Periodic Reviews

During this audit it was found that monthly supervisory reviews of certified establishments were being performed and documented as required. However, it was noted upon the review of the last twelve monthly supervisory reports that the CCA audits did not adequately identify/corrected EU and FSIS requirements in the risk areas related to sanitary operation, light, ventilation, ante-mortem, and humane handling in the certified establishments.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

The following non-compliance was reported:

- U.S. and E.C. requirements pertinent to sanitary operation, light, ventilation, ante-mortem, and humane handling were not adequately enforced in certified establishments audited.

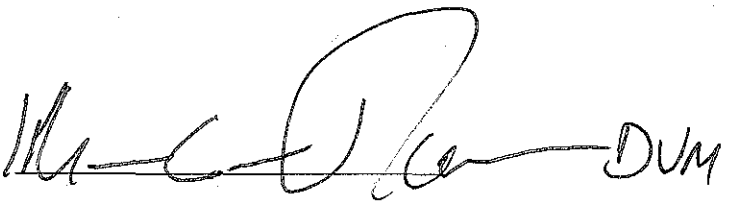
In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. EXIT MEETING

An exit meeting was held on August 12, 2009, in Helsinki with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.



Alam R. Khan, DVM
Senior Program Auditor

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Reports
Foreign Country Response to Draft Final Audit Report (When it becomes available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Atria Oyj PL 900 Nurmo 60550	8/4/09	22	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam R. Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 8/4/09 Est #: 22 (Atria Oyj []) (Nurmo, Finland)

10/51 a) In the employee sanitation room, the ready to use hand tools including knives, steels and aprons and gloves had blood, fat and unidentified organic particles on their surfaces. The interior of the scabbard was un-cleaned. The entire supply of tools and accessories was removed for cleaning and re-presented for pre-op. The second presentation, again, still had residues that were not completely removed. The establishment provided the new set of tools to each employee to get work started. .
b) Several knife sanitizers in the evisceration room were either unclean with a greasy surface or contained water from the previous day's work were posing potential for contamination. Neither the establishment's nor local inspection's pre-op records identified this observation. The review of the establishment and local inspection's SSOP records for the last sixty days did not reveal similar incidents. Except for minor deficiencies that did not impact public health, the establishment's records did not identify any trend of non compliance. The review of monthly supervisory visits did not identify problems with pre-operational sanitation. [Regulatory reference(s): 9 CFR §416.13]

22/51 The establishment's designated employee for calibrating thermometer did not document time, date or results on several occasions. [Regulatory reference(s): 9 CFR §417.5]

40/51 All light fixtures over the swine finish line were dirty, cracked, and had several dead flies stuck to their inner surfaces creating insanitary operational conditions and posing potential for product contamination. This issue was not addressed in any of the establishment's maintenance records.
The establishment replaced all light fixtures with new ones. The review of the establishment's pest management program indicated the entry of flies in the different part of the facility despite the use of UV traps.
[Regulatory reference(s): 9 CFR §416.2(c)] [EC Directive 64/433, Annex 1, Chap 1]

41/51 Beaded condensation was observed on the overhead structures above the exposed product at more than three locations within the processing room as well as on the carcass rail exiting a cooler. The product stored under the affected area was potentially exposed to contamination from the condensation. The establishment addressed the problem immediately and removed the product from the affected areas. The review of the establishment's and local inspection's daily records did not indicate condensation to be a problem.
[Regulatory reference(s): 9 CFR §416.2(d)] [EC Directive 64/433, Annex 1, Chapter 1, 1(n)]

46/51 a) The steam cabinets for scalding pigs had a thick layer of grime build up in their interiors was creating insanitary conditions. This observation was not identified in any of the maintenance programs maintained by the establishment. This concern was immediately addressed by the establishment by using pressure hosing on the steam cabinets. The use of pressured water to clean cabinets will be incorporated into the SOP.
b) In the chemical storage room located near the swine hoist line, rusty shelves were littered with miscellaneous articles were creating insanitary conditions and potentials for the product contamination. In an adjacent room, a chemical barrel of motor oil was stored directly on the floor creating insanitary conditions and potential for product contamination during the handling or spillage of the chemical.
[Regulatory reference(s): 9 CFR §416.4 (a)] [EC Directive 64/433, Chapter III (3)]

58 The Finnish Food Authority issued the establishment a Notice to Delist (NOID) due to the SSOP, SPS non-compliance noted during the audit.

61. NAME OF AUDITOR
Alam R. Khan, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
HK Ruokatalo Oy Ysitie 387A Mellila 32300	8/7/09	85	Finland
	5. NAME OF AUDITOR(S) Alam R. Khan, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 8/7/09 Est #: 85 (HK Ruokatalo Oy [S/P]) (Mellila, Finland)

15/51. The establishment had not conducted the hazard analysis for the ear removal/stamping step as shown in the flow diagram. The review of Evira's inspection staff records did not indicate the aforementioned non-compliance from HACCP requirements. [Regulatory reference(s): 9 CFR §417.2(c)]

46/51. a) Several hoisting hooks on the slaughter line were observed to be covered with a massive amount of pig hairs during the pre-operational verification. Hair accumulation on the hooks was creating insanitary operational conditions and was posing a potential for product contamination. b) The tufts of hair found enmeshed around the shaft, chain and other parts of the de-hairer machine during pre-operational verification were posing insanitary operational conditions. The review of SSOP/SOP plans and the monitoring records revealed that such hair accumulation within the de-hairer is permitted for a week before being subjected to thorough weekly cleaning. According to Finnish legislation, such practices are permitted. [9 CFR §416.4(a)] [EC Directive 64/433 Annex 1 Chap 3 (c)]

52/51. Protruding bolts on a restraining steel gate were observed at the unloading dock. The bolts were posing potential for injuries to pigs during the unloading process. The inspection staff records did not identify this to be a concern. The establishment gave assurances that the bolts would be filed and evened with the gate. [9 CFR §313] [EC Directive 64/433]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam R. Khan, DVM	DVM

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
HK Ruokatalo Oy Teollisuuskatu 17 Forssa 30420	8/10/09	18	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam R. Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment Date: 8/10/09 Est #: 18 (HK Ruokatalo Oy [S/P]) (Forssa, Finland)

15/51. a) The establishment slaughters suspect animals separately from the slaughter line near the suspect pen. The stunned, stuck and bled suspect animals are transported and hung on slaughter line with the healthy pigs. This step was neither shown on the flow diagram nor was a hazard analysis conducted. b) The establishment reworks meat product; however, the hazard associated with this step was neither on the flow diagram nor was a hazard analysis conducted. [Regulatory reference(s): 9 CFR §417.2(c)]

38/39/46. a) During the handling of meat affected with an abscess, an employee, after handling a water hose, proceeded to handle meat without changing his gloves which was not consistent with the establishment's standard operating procedures and could result in product contamination b) Rolls of clear plastic sheet described to be used for shipping product stored on the loading dock. Another such roll covered in dirt was left unattended between a post and the wall near packing room. The rolls could potentially be used in handling and packaging edible products and could, therefore, potentially contaminate/adulterate product. c) A barrel of an unidentified chemical was stored in the shipping area; the contents, therein, can be misused resulting in contamination of the product. d) In a processing room, edible containers were stored on top of a chemical tank without a lid. The containers were exposed to chemicals and therefore may indirectly contaminate the product. The plant and inspection record did not identify the findings listed as items b and c. All findings were immediately corrected. [9 CFR §416.2(b)]

41/51. a) The over head structure in a carcass cooler had beaded condensation above the exposed carcasses. Although, no direct product adulteration was observed at the time of audit, condensation could contaminate the product stored under the affected area. A similar finding was noted during the last year audit of this establishment. Immediate corrective action was taken. Review of the establishment's SSOP and SOP documents for up to 90 days did not identify any trend related to the findings. Except for sporadic citing of condensation in the documents, there were no distinct concerns on the issue b) In the MDM room, overhead exhaust conduits were corroded at two different locations resulting in holes with avulsing rusty content in close proximity to tanks containing edible product. The corroded material from the overhead exhaust could potentially contaminate the product stored or being processed in the room. In the same room a pipe connecting to a cooling condenser was leaking; the leakage was dripping onto utensils and containers for edible product. The affected scoops could have been utilized in handling the edible product as similar scoops are used plant-wide. The containers loosely covered with plastic liners may have received splashes from the leakage. The establishments or inspections record did not identify the findings. Immediate corrective actions were initiated by the establishment. [9 CFR §416.2(d)] [EC Directive 64/433, Annex 1, Chapter 1]

52/51 The provisions of Finnish Animal Welfare Degree (396/1996) were not complied with. In the absence of feeders it could not be determined how the pigs that were kept more than 12 hours or over the weekend in the establishment were fed as required under the aforementioned provisions. Keeping pigs over 24 hours without providing feed is inconsistent with humane handling of livestock practices. [9 CFR §313.2 (e)][EC Directive 64/433, Annex 1, Chapter 1]

54/51. a) The review of more than six months worth of ante-mortem records maintained at the local inspection office revealed that a thermometer is not utilized during ante-mortem inspection. The lack of thermometer use allows for swine running a temperature of 106 °F or more proceeding for slaughter. FSIS regulation requires any swine having a temperature of 106°F or higher shall be identified and condemned on ante-mortem b) A pig reported of having received ante-mortem inspection but suspected of being sick was stunned, stuck, and bled outside the stunning area. Blood spilled onto the floor can collect within the boots of employees and thus spread to live animals in the pens. [9 CFR §309] [EC Directive 64/433, Annex 1, Chapter 4]

58. The Finnish food authority EVIRA, issued the establishment an NOID due to the non-compliances identified during the audit.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam R. Khan, DVM	DVM

Evira

Meat Inspection Unit	Pvm/Datum/Date	Dnro/Dnr/DNo
	2.11.2009	7344/0028/2009

Mr. James Adams
Director, International Audit Staff
Office of International Affairs
Food Safety and Inspection Service

1400 Independence
20250 WASHINGTON, D.C.

THE DRAFT AUDIT REPORT FOR FINLAND JULY 29 TO AUGUST 12, 2009

Dear Mr. Adams,

Please find enclosed the comments of the Finnish Food Safety Authority on the draft audit report 2009:

Please kindly check that the page numbering in contents corresponds to the text.

1. SUMMARY
1.1 Description/Eligibility

First paragraph, fourth sentence should read: Between January 1 and July 31, 2009, Finland exported 8,686,377 pounds of meat to the United States, of which 3,670,054 pounds were reinspected at US ports of entry (POE). Finland is not eligible to export *poultry products* to the United States.

Second paragraph, first sentence should read: The findings of the previous audit during *May 2008* resulted in no restrictions of the ability of any establishment in Finland to export meat products to the US.

6 MAIN FINDINGS
6.2.3 Assignment of Competent, Qualified Inspectors

In Finland, veterinarians take courses in meat inspection in the curriculum of their formal education. After graduation they take further special courses in meat inspection including four weeks of practical training. They must pass specific examinations before being qualified to work in establishments.

After graduation, veterinary surgeons are immediately eligible to work in slaughterhouses, as they will have already completed a practical training period in a slaughterhouse and an examination, as part of their course. However, an extra four weeks'

Elintarviketurvallisuusvirasto Evira
Mustialankatu 3, 00790 HELSINKI
Puh. 020 690 999 • Faksi 020 77 24350
etunimi.sukunimi@evira.fi • www.evira.fi

Livsmedelssäkerhetsverket Evira
Mustialagatan 3, 00790 HELSINGFORS
Tel. 020 690 999 • Fax 020 77 24350
förnamn.efternamn@evira.fi • www.evira.fi

Finnish Food Safety Authority Evira
Mustialankatu 3, FI-00790 HELSINKI, Finland
Tel. +358 20 690 999 • Fax +358 20 77 24350
firstname.lastname@evira.fi • www.evira.fi

practical training in a slaughterhouse and a specific test are considered an advantage, when a veterinarian applies for a job in a slaughterhouse.

The FSA organizes every year a one-day training course to provide additional training on U.S. export issues to inspection personnel and establishment personnel.

In November 2007, a one-day training course was organized and presented by the FSA to provide additional training on U.S. export issues including HACCP, SSOP and SPS requirements to both inspection personnel and establishment personnel.

The FSA would like to add the following:
Also in November 2008, a one-day training course was organized and presented by the FSA to provide additional training on U.S. export issues including HACCP, SSOP and SPS requirements to both inspection personnel and establishment personnel.

The FSA would like to add the following:
The FSA organizes every year two-day training courses for official veterinarians twice a year. For auxiliaries, the FSA organizes similar two-day training courses in spring and autumn.

In November 2007, a two-day training course was organized by the FSA to provide additional training in various subjects, such as animal diseases animal welfare to official veterinarians in slaughter houses.

In March 2008, a two-day training course was organized by the FSA to provide training to auxiliaries in slaughter houses regarding the new organization of FSA, meat inspection, residues, and animal diseases.

In April 2008, a two-day training course was organized by the FSA to provide training to official veterinarians in slaughter houses regarding the new organization of FSA, meat transportation, and matters related to maintaining ability to work.

The FSA would like to add the following:
In October 2008, the FSA ran training days for official veterinarians and in October and November 2008 for auxiliaries. The official veterinarians' course topics included slaughterhouses' preparedness plans in case of animal diseases, making a meat inspection decision, EU animal welfare inspections during transport, and various group exercises. The auxiliaries' training included post mortem examinations of various animal species, animal diseases, and occupational health and wellbeing issues.

In March 2009, the FSA ran training days for official veterinarians, focusing on animal diseases, animal welfare, and animal transport inspections. In February and March 2009, the FSA organized training days for auxiliaries, covering animal diseases, occupational wellbeing, 2009 audits of the Meat Inspection Unit, and issues related to slaughterhouses' contingency plans in case of animal diseases.

9.3 EC DIRECTIVE 64/433

Non compliances with the requirements for humane handling were found in two of three establishments audited and summarized below.

Bullet point two: in one establishment: The feeders were not provided for the pigs held over 24 hours or on weekends. Keeping pigs over 24 hours without providing feed is inconsistent with humane handling of livestock practices.

The FSA would like to add the following:
Finnish Animal Welfare Degree (396/1996) demands that if animals are not slaughtered within 12 hours from their arrival at a slaughterhouse or place of slaughter, they must be given enough feed upon their arrival and after this they must be fed at intervals suited to the animal species concerned and milked, where necessary. The condition and state of health of animals to be slaughtered must be checked daily in the morning and evening and, where necessary, even more frequently. There is no exact demand in legislation that there have to be feeders in a slaughterhouse. Of course there have to be a possibility to feed animals in such a way that the feed isn't contaminated with faeces and urine. It has also been recommended that then there are feeders those are situated beside the walls and so that there are enough feeders for the animals to eat undisturbed.

11. SLAUGHTER/PROCESSING CONTROLS
11.2 Humane Handling and Humane Slaughter

Bullet point one: in one of the three establishments audited, the feeders were not provided for the pigs held over 24 hours or on weekends. The local inspection staff record did not mention the absence of the feeders.

The FSA would like to add the following:
Finnish Animal Welfare Degree (396/1996) demands that if animals are not slaughtered within 12 hours from their arrival at a slaughterhouse or place of slaughter, they must be given enough feed upon their arrival and after this they must be fed at intervals suited to the animal species concerned and milked, where necessary. The condition and state of health of animals to be slaughtered must be checked daily in the morning and evening and, where necessary, even more frequently. There is no exact demand in legislation that there have to be feeders in a slaughterhouse. Of course there have to be a possibility to feed animals in such a way that the feed isn't contaminated with faeces and urine. It has also been recommended that then there are feeders those are situated beside the walls and so that there are enough feeders for the animals to eat undisturbed.

11.3 HACCP Implementation

Bullet point two: in one establishment, the hazard associated with the rework step for certain meat dropped on the floor was neither on the flow diagram nor was a hazard analysis conducted.

The FSA would like to add the following:
Based on recent investigations carried out by the FSA, it takes the view that dropped pieces of meat or carcasses do not need to be separately entered in the slaughter-

house or cutting room HACCP flow chart and hazard analysis. All export slaughter-houses for the USA have applied the SSOP directions under the SSOP Program on how dropped pieces of meat or carcasses are dealt with. According to the view of the FSA this procedure should fulfill the requirements.

Yours sincerely,

Head of Unit
Meat Inspection Unit

Eeva-Riitta Wirta

Senior Officer
Meat Inspection Unit

Sirpa Kemilä