



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Ms. Auli Vaarala
Director, Hygiene Unit, Control Department
Finnish Food Safety Authority, EVIRA
Mustialankatu 3
FI-00790 Helsinki
Finland

MAR - 5 2009

Dear Ms. Vaarala :

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Finland's meat inspection system May 14 through May 29, 2008. Comments from the government of Finland have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

Manzoor Chaudry, DVM
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

MAR - 5 2009

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

MAY 14 THROUGH MAY 29, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [Finnish Food Safety Authority (EVIRA)]
DDG	Deputy Director General
<i>E. coli</i>	<i>Escherichia coli</i>
EC	European Commission
EVIRA	Finnish Food Safety Authority
FINAS	Finnish Accrediting Service
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
<i>Salmonella</i>	<i>Salmonella</i> species
SO	Senior Officer
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U.S.	United States
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Finland from May 14 through May 29, 2008.

An opening meeting was held on May 14, 2008, in Helsinki with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed 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 (EVIRA).

2. OBJECTIVE OF THE AUDIT

This was a routine audit with special emphasis on humane handling and slaughter of livestock. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States (U.S.).

In pursuit of the objective, the following sites were visited: the headquarters of the CCA; four local inspection offices; one private microbiology laboratory performing analytical testing on United States-destined product; one government residue laboratory conducting analyses of field samples for Finland's national residue control program; three swine slaughter/processing establishments; and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	1	Helsinki
	Local	4	Establishment level
Laboratories		2	Microbiology and residue laboratory
Meat Slaughter and Processing Establishments		3	
Cold Storage Facility		1	

3. PROTOCOL

This on-sight 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 headquarters. The third part involved on-site visits to three swine slaughter/processing establishments and one cold storage facility. The fourth part involved visits to one private microbiology laboratory and one government residue laboratory.

Program effectiveness determinations of Finland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS); (2) animal disease controls; (3) slaughter/processing controls, including the implementation and

operation of Hazard Analysis and Critical Control Point (HACCP) programs and a testing program for generic *Escherichia coli* (*E. coli*); (4) residue controls, and (5) enforcement controls including a testing program for *Salmonella* species (*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 auditor 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 opening meeting, the auditor explained to the CCA that the Finnish 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 Food Safety Inspection Service (FSIS) requirements. These include daily inspection in all certified establishments, humane handling and slaughter of livestock, the handling and disposal of inedible and condemned materials, species verification, and FSIS's requirements for HACCP, SSOP, SPS, 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.
- Testing for *Enterobacteriaceae* and Total Viable Count in lieu of testing for generic *E. coli* is acceptable for all EU exporting countries.
- The use of an alternate laboratory testing method ISO 6579:2002(modified) for *Salmonella*. In addition, FSIS has granted Finland an equivalence determination allowing the use of methods ISO 6579:1993 and NMKL 71 (dated 1999) for *Salmonella*.
- The use of methods NMKL 147:1993 for generic *E. coli* and NMKL 144, 3rd addition 2005 for *Enterobacteriaceae*.
- The use of private laboratories for the analysis of official samples.

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 β -agonists.”

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS website at the following address:

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

The following deficiencies were reported during the FSIS audit of Finland’s meat inspection system conducted in November 2005:

- One establishment received a Notice of Intent to Delist (NOID).
- The National Food Agency (NFA) needed to continue training in HACCP and SSOP requirements since deficiencies in these areas were still identified in three of the audited establishments.
- In three of four establishments audited, inspectors were not fully enforcing FSIS requirements relating to HACCP, SSOP and microbial testing programs.
- The CCA was not providing direct oversight over the laboratories conducting testing of meat products destined for the United States. This function was performed by the Finnish Accrediting Service (FINAS), which is an independent ISO accrediting body. FINAS provides ISO 17025 accreditation and conducts annual audits. It does not address specific needs for the U.S. export testing program.
- In two of four establishments audited, deficiencies were reported for the implementation of SSOP.
- In one of four establishments audited, deficiencies were reported for SSOP recordkeeping.
- In one of the establishments audited, boxes for edible product were stored with interior surface up, and some boxes were covered by a thin layer of dust in the storage room.
- In one of four establishments audited, some of the EC Directive 64/433 provisions were not implemented.
- In three of four establishments audited, some of the HACCP requirements were not implemented.
- *Salmonella* testing: Two of the four laboratories audited did not use positive and negative controls with each group of U.S. export samples.
One of four laboratories audited did not perform biochemical confirmation on site.

Until the day prior to the audit, records indicated that excessive temperature tolerance had been allowed for incubation of RVS Broth, although excessive temperatures were not found in these records. If, in the opinion of the laboratory, method tolerance ranges cannot be reliably achieved, analyses cannot be regarded as valid.

- In one of four laboratories audited, thermometer error was not annotated on temperature records. Working thermometers and balances were not calibrated annually (EA 04/10). For each prepared batch of media, autoclave records were not clearly traceable to other media preparation records.

These specific deficiencies were found to have been corrected by the May 2007 FSIS audit.

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 a build-up of organic material.
- In one establishment, excessive hair was observed on the ham and belly areas of two swine carcasses in the coolers.
- In one establishment, the time when the pre-operational sanitation inspection was performed in the cutting room was not recorded as required in the establishment's written program.
- In one establishment, flaking paint and rust were observed on a wall in the dry storage room.
- In one establishment, white working clothes and street clothes were hanging together in an employee locker room, causing insanitary conditions.
- In one establishment, white powder (in an approximately two-foot-square area) was observed on the floor in the dry storage room.
- 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.
- In one establishment, it was not clear in the HACCP records that verification is conducted for record review or for direct observation for CCP1.

In both establishments audited, the provisions of EC Directive 64/433 were not effectively implemented. The following deficiencies 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 a build-up 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.

Establishment Number 18 laboratory performs testing on samples from Establishments Number 18 and 85. The following deficiency was observed:

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

These specific deficiencies were found to have been corrected by the May 2008 FSIS audit.

6. MAIN FINDINGS

6.1 Legislation

The Food Safety Authority (FSA) 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 following is a list of 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 been divided into the following three new departments since January 1, 2008.

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

All these new departments are sectioned into several units.

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

6.2.1 CCA Control Systems

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

The meat inspection personnel have become a part of the new MIU, which is directly under the supervision of the 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 European Union. The in-plant inspection personnel are now supervised by the FSA Senior Officers stationed at the FSA Headquarters in Helsinki.

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

Nationally developed inspection forms for supervision of establishment compliance are in use in all establishments. The written guidelines 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, 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. Non-veterinary "auxiliaries" have courses involving 200 hours of practical training on the slaughter line and 400 hours of theoretical classwork, after which they must also pass specific examinations before being qualified to work in export meat establishments.

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.

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 slaughterhouses.

In March 2008, a two-day training course was organized by the FSA to provide training to auxiliaries in slaughterhouses 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 slaughterhouses regarding the new organization of FSA, meat transportation, and matters related to maintaining ability to work.

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 the FSIS regulatory requirements in establishments certified to export to the United States. FSA not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval 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 record reviews focused on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspectors and laboratory personnel.
- 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.

There were no concerns arising as a result of the examination of these documents.

6.3.1 Audits of Regional and Local Inspection Sites

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited three slaughter/processing establishments, and one cold storage facility. None of the establishments were delisted by Finland's inspection service as a result of failure to meet FSIS and EC requirements. None of the establishments received a Notice of Intent to Delist (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.

Microbiology laboratory audits focus 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 U.S. samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following laboratories were audited:

The Government Residue Laboratory "Research Department Chemistry and Toxicology" located in Helsinki.

No deficiencies were reported.

A private microbiology laboratory "HK RUOKATALO OY" which conducts *Salmonella* and generic *E. coli* testing of porcine carcasses located at Establishment Number 18 in Forssa.

Establishment Number 18 laboratory performs testing on samples from Establishments Number 18 and 85. The following deficiency was reported:

- There were rusty baskets for the storage of small laboratory utensils in the cabinets and rusty hooks attached to the wall.

9. SANITATION CONTROLS

As stated earlier, the 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, and 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 records, back-siphonage prevention, separation of operations, temperature control, workspace, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

Specific deficiencies are reported on the attached individual establishment checklists.

9.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in all three of the three establishments required to have SSOP were found to meet the basic FSIS regulatory requirements, with the following deficiency in the implementation of SSOP:

- In one establishment, pieces of pork fat were observed on cleaned and ready-to-use metal hooks in the cutting room.

9.2 Sanitation Performance Standards

The following deficiencies were reported:

- In one establishment, pieces of meat and fat were observed on the floor in the cutting room during pre-operational sanitation.
- Heavily beaded condensate was observed on the overhead structure above the tails and leaf fat containers in the offal chilling room.
- Rusty metal and pieces of rust were observed inside the employees' time clock cabinet in the cutting room.
- In one establishment, boxes and office files were stored in a manner which precluded inspection in the upper level of the dry storage room for possible pest control problems.
- Rough welding was observed on product contact surfaces on several pieces of equipment in the cutting room.
- A metal container used for inedible product in the cutting room did not bear conspicuous and distinctive markings.

- A wall-mounted file cabinet in the cutting room had a build-up of mold and product residues.
- Street and working clothes were hanging together in an employee's locker.
- Aprons used to cover the employees' metal chest protection had been torn and were not readily cleanable.

9.3 EC Directive 64/433

In two establishments audited, the provisions of EC Directive 64/433 were not effectively implemented. The following deficiencies were reported:

- Pieces of pork fat were observed on cleaned and ready-to-use metal hooks in the cutting room.
- Pieces of meat and fat were observed on the floor in the cutting room during pre-operational sanitation.
- Heavily beaded condensate was observed on the overhead structure above the tails and leaf fat containers in the offal chilling room.
- Rusty metal and pieces of rust were observed inside the employees' time clock cabinet in the cutting room.
- Rough welding was observed on product contact surfaces on several pieces of equipment in the cutting room.
- A wall-mounted file cabinet in the cutting room had a build-up of mold and product residues.
- Street and working clothes were hanging together in an employee's locker.
- Aprons used to cover the employees' metal chest protection had been torn and were not readily cleanable.

See the attached individual establishment checklists for specific deficiencies.

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 reported.

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 humane slaughter of livestock; 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 Humane Handling and Humane Slaughter

No deficiencies were reported regarding the humane handling or humane slaughter of livestock.

11.2 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 the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of three establishments. The following deficiency was reported:

- In one establishment, the hazard analysis was incomplete in the consideration of zero tolerance for visible fecal, ingesta, and milk.

11.3 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 measures:

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

The establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

The following deficiency was reported:

- In one establishment, the sequence of swine carcass sponging for generic *E. coli* was not being followed as required (ham, belly and jowl).

11.4 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.

11.5 EC Directive 64/433

In one establishment, the provision of EC Directive 64/433 regarding post-mortem inspection was not implemented. The following deficiency was reported:

- A government inspector was not observing and palpating the mesenteric lymph nodes at the swine post-mortem inspection station.

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.

No deficiencies were reported.

Finland's National Residue Control Program was being followed and was on schedule.

12.1 EC Directive 96/22

In the government residue laboratory "Research Department Chemistry and Toxicology" the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the government residue laboratory "Research Department Chemistry and Toxicology", the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor 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]) In addition, FSIS

has granted Finland an equivalence determination allowing the use of methods ISO 6579:1993 and NMKL 71 (dated 1999) for *Salmonella*.

- Finland may allow either establishment or government employees who are fully trained to take samples applicable to *Salmonella* testing program.

Three of the four establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

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

Periodic supervisory reviews of certified establishments were being performed and documented as required.

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 deficiency was reported:

- In one establishment, a government inspector was not observing and palpating the mesenteric lymph nodes at the swine post-mortem inspection station.

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 countries 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. CLOSING MEETING

A closing meeting was held on May 29, 2008, 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.

Farooq Ahmad, DVM
Senior Program Auditor

A handwritten signature in blue ink, reading "Farooq Ahmad DVM", is written over a horizontal line.

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Reports

Foreign Country Response to Draft Final Audit Report

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION
HK Ruokatalo Oy
Teollisuuskatu 17
Forssa 30420

2. AUDIT DATE
5/21/2008

3. ESTABLISHMENT NO.
18

4. NAME OF COUNTRY
Finland

5. NAME OF AUDITOR(S)
Farooq Ahmad, DVM

6. TYPE OF AUDIT
 ON-SITE AUDIT DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	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	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
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

Date: 5/21/2008 Est #: 18 (HK Ruokatalo Oy [S/P]) (Forssa, Finland)

10/56. Pieces of pork fat were observed on ready-to-use metal hooks in the cutting room. Government officials took immediate corrective actions. [Regulatory references: 9 CFR 416.13 and EC Directive 64/433, ANNEX 1, CHAPTER 111.3]

41/46/56. (a) Heavily beaded condensate was observed on the overhead structure above the tails and leaf fat containers in the offal chilling room. Government officials took immediate corrective actions. [9 CFR 416.4(d) and EC Directive 64/433, ANNEX 1, CHAPTER 1(n)]

(b) Rusty metal and pieces of rust were observed inside the employees' time clock cabinet in the cutting room. Government officials assured immediate corrective actions. [9 CFR 416.4(b) and EC Directive 64/433, ANNEX 1, CHAPTER 111.3]

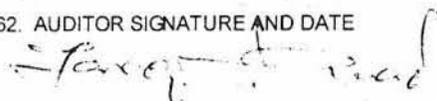
(c) Pieces of meat and fat were observed on the floor in the cutting room during pre operational sanitation. Government officials took immediate corrective actions. [9 CFR 416.4(b) and EC Directive 64/433, ANNEX 1, CHAPTER 111.3]

55/51. A government inspector was not observing and palpating the mesenteric lymph nodes at the swine post-mortem inspection station. Government officials took immediate corrective actions. [9 CFR 310.1 and EC Directive 64/433, ANNEX 1, CHAPTER VI, 23(b) 25(g)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 12/22/2008

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION: Atria Oy, Lapuantie 594, Nurmo 60550
 2. AUDIT DATE: 5/19/2008
 3. ESTABLISHMENT NO.: 22
 4. NAME OF COUNTRY: Finland
 5. NAME OF AUDITOR(S): Farooq Ahmad, DVM
 6. TYPE OF AUDIT: ON-SITE AUDIT DOCUMENT AUDIT

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

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

Date: 5/19/08 Est #: 22 (Atria Oy [S/P]) (Nurmo, Finland)

28. The sequence of swine carcass sponging for generic *Escherichia coli* was not being followed as required (ham, belly and jowl). The government officials took immediate corrective actions. [Regulatory References: 9 CFR 310.25(a)(ii)(C)]

38/51. Boxes and office files were stored in a manner which precluded inspection of the upper level of the dry storage room for possible pest control problems. The government officials assured immediate corrective actions. [9 CFR 416.2(a)]

45/56. (a) Rough welding was observed on product contact surfaces on several pieces of equipment in the cutting room. The government officials assured immediate corrective actions. [9 CFR 416.3(a) and EC Directive 64/433, Annex 1, Chapter II (n)]

(b) A metal container in the cutting room used for inedible product did not bear conspicuous and distinctive markings. The government officials took immediate corrective actions. [9 CFR 416.3(c)]

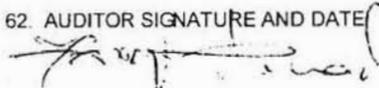
46/56. A wall-mounted file cabinet in the cutting room had a build-up of mold and product residues. The government officials took immediate corrective actions. [9 CFR 416.4(b) and EC Directive 64/433, Annex 1, Chapter III.3]

47/56. (a) Street and working clothes were hanging together in an employee's locker. The government officials took immediate corrective actions. [9 CFR 416.5(b) and EC Directive 64/433, Annex 1, Chapter III, 3]

(b) Aprons used to cover the employees' metal chest protectors had been torn and were not readily cleanable. The government officials took immediate corrective actions. [9 CFR 416.5(b) and EC Directive 64/433, Annex 1, Chapter III, 3]

61. NAME OF AUDITOR
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



12/22/2008

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Ruokatalo Oy Ysitie 387a Mellila 32300	2. AUDIT DATE 5/23/2008	3. ESTABLISHMENT NO. 85	4. NAME OF COUNTRY Finland
	5. NAME OF AUDITOR(S) Farooq Ahmad, DVM	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	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	
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	
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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

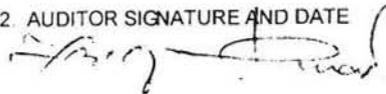
60. Observation of the Establishment

Date: 5/23/2008 Est #: 85 (HK Ruokatalo Oy [S/P/CS]) (North Boundary, Finland)

15/51. The hazard analysis was incomplete in the consideration of zero tolerance for visible fecal, ingesta, and milk.
[Regulatory references: 9 CFR 417.2, 417.8]

61. NAME OF AUDITOR
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



12/22/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION
Pakastamo Oy
Teollisuuskatu 17
Forssa 30420

2. AUDIT DATE
5/22/2008

3. ESTABLISHMENT NO.
S 061101

4. NAME OF COUNTRY
Finland

5. NAME OF AUDITOR(S)
Farooq Ahmad, DVM

6. TYPE OF AUDIT
 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)		Audit Results	Part D - Continued Economic Sampling		Audit Results
Basic Requirements			Part E - Other Requirements		
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 F - Inspection 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 SSOPs have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan.		()	41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		()	42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.		()	43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.		()	44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
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 G - Other Regulatory Oversight Requirements		
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		()	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		
24. Labeling - Net Weights			52. Humane Handling		()
25. General Labeling			53. Animal Identification		()
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park 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		
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

Date: 5/22/2008 Est #: S 061101 (Pakastamo Oy [F]) (Forssa, Finland)

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

61. NAME OF AUDITOR
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



5/22/2008

Letter

Meat Inspection Unit

Pvm/Datum/Date
11.2.2009Dnro/Dnr/DNo
1179/0929/2009

Mr. Donald Smart
Director, International Audit Staff
Office of International Affairs
Food Safety and Inspection Service

1400 Independence, SW, Room 3805-South
Washington, DC 20250

THE DRAFT AUDIT REPORT FOR FINLAND MAY 14 - 29, 2008

Dear Mr. Smart,

Please find enclosed the comments of the Finnish Food Safety Authority on the draft audit report 2008:

1. INTRODUCTION

Third paragraph, first sentence should read: The auditor was accompanied during the entire audit by representatives from the CCA, the Finnish Food Safety Authority "EVIRA".

3. PROTOCOL

Sixth paragraph, bullet point three should read: 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 ISO 6579:1993 and NMKL 71 (dated 1999) for *Salmonella*.

Sixth paragraph, bullet point four should read: The use of methods NMKL 147:1993 for generic *E. coli*, NMKL 144, 3rd addition 2005 for *Enterobacteriaceae* and NMKL 86:2006 for Total Viable Count.

9. SANITATION CONTROLS

9.1 Sanitation Standard Operating Procedures

First paragraph, second sentence should read: The SSOP in *four* establishments were found to meet the basic FSIS regulatory requirements, with the following deficiency in the implementation of SSOP:

Letter

Meat Inspection Unit

Pvm/Datum/Date
11.2.2009Dnro/Dnr/DNo
1179/0929/2009

13. ENFORCEMENT CONTROLS

13.2 Testing for *Salmonella*

First paragraph, bullet point one should read: FSIS has granted Finland an equivalence determination allowing the use of an alternate laboratory testing method for *Salmonella* (ISO 6579:2002 (modified)). *In addition FSIS has granted Finland an equivalence determination allowing the use of methods ISO 6579:1993 and NMKL 71 (dated 1999) for Salmonella.*

Yours sincerely,

Head of Unit
Meat Inspection Unit

Eeva-Riitta Wirta

Senior Officer
Meat Inspection Unit

Sirpa Kemilä