Washington, D.C. 20250

SEP 1 8 2007

Dr. Osmo Mäki-Petäys
Director, Meat and Fish Hygiene Unit
National Veterinary & Food Research Institute
Hameentie 57
Fin-00231 Helsinki, Finland

Dear Dr. Mäki-Petäys:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Finland's meat inspection system May 7 to May 21, 2007. Comments from 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 (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

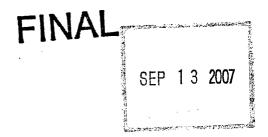
Donald Smart

Director

International Audit Staff

Office of International Affairs

Enclosure



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

May 7 through May 21, 2007

Food Safety and Inspection Service United States Department of Agriculture

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- 14. CLOSING MEETING
- 15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA Central Competent Authority [Finnish Food Safety Authority (FSA)]

E. coli Escherichia coli

FINAS Finnish Accrediting Service

FSA Food Safety Authority

FSIS Food Safety and Inspection Service

NFA National Food Agency

NOID Notice of Intent to Delist

PR/HACCP Pathogen Reduction/Hazard Analysis and Critical Control Point System

Salmonella Salmonella species

SO Senior Officer

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 7 through May 21, 2007.

An opening meeting was held on May 7, 2007, 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. 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, two local inspection offices, one private microbiology laboratory performing analytical testing on United States-destined product, one government microbiology laboratory providing information for export laboratories on international standards and methods, and two swine slaughter/processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Helsinki
	Local	2	Establishment level
Laboratories		2	Microbiology laboratories.
Meat Slaughter and Processing Establishments		2	
Cold Storage Facilities		0	

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 two swine slaughter/ processing establishments. The fourth part involved visits to two microbiology laboratories (one government and one privately owned 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), (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 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 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 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 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: FSIS has granted Finland an equivalence determination allowing the use of ISO 6579:2002(E) 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*.

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 Community 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 βagonists"

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 deficiencies were reported during the FSIS audit of Finland's meat inspection system conducted in February/ March 2005:

- One slaughter/processing establishment was issued a Notice of Intent to Delist (NOID) for various deficiencies; most notable were direct product contamination and dripping beaded condensate over product areas.
- Four establishments were cited for inadequate enforcement of FSIS inspection requirements, such as HACCP, SSOP and other sanitation requirements.
- Some sanitation deficiencies previously observed and documented, e.g., direct product contamination) remained uncorrected.
- Veterinarians assigned to all FSIS-certified establishments appeared to lack adequate knowledge of FSIS requirements.

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).
- NFA needs 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 U.S. 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
 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 four 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: In two of four laboratories audited, the laboratories did not use positive and negative controls with each group of U.S. export samples. In one of four laboratories audited, the laboratories 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.
- In three of four establishments audited, inspectors were not fully enforcing FSIS requirements relating to HACCP, SSOP and microbial testing programs.

6. MAIN FINDINGS

6.1 Legislation

The FSA has completed new 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 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 Food Safety Authority (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 new FSA, 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.

All these departments are sectioned in to several units.

The former NFA have become part of the Department of Food and Veterinary Control. The FSA is responsible for uniform implementation of field to table controls employing risk assessment procedures.

6.2.1 CCA Control Systems

The Department of Food and Veterinary Control in the FSA has been separated into the units of Animal Health and Welfare, Food Hygiene, Meat and Fish Hygiene, Product Safety and Marketing and Food Control and Veterinary Services, since May 2006. The meat inspection personnel became the part of this new Department of Food and Veterinary Control, under the Meat and Fish Hygiene unit.

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 include meat inspection in slaughterhouses and approval of the slaughterhouses and connected establishments. Municipal control authorities are responsible for approval of other establishments and meat inspection in small slaughterhouses. 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 U.S. 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 are in use in all establishments for supervision of establishment compliance. New 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 developed and implemented.

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 class work, after which they must also pass specific examinations before being qualified to work in export meat establishments.

In September 2006, 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 March 2007, a one-week training course was organized by the FSA to provide additional training in HACCP SSOP, and SOP requirements and verification for inspection and establishment personnel. This course was presented by an outside consulting organization and included both classroom and hands-on training.

6.2.4 Authority and Responsibility to Enforce the Laws

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

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 inplant 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 and laboratory personnel
- Animal disease status
- Supervisory visits to U.S.-certified establishments
- 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

Any concerns arising as a result of the examination of these documents are noted in appropriate sections of this report.

6.3.1 Audits Regional and Local Inspection Sites

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

7. ESTABLISHMENT AUDITS

The FSIS auditors visited two slaughter/cutting establishments. Neither of the two establishments was delisted by the Finland's Inspection Service as a result of failure to meet FSIS requirements. Neither of the two establishments received a Notice of Intent to Delist (NOID) from the Finland's Inspection Service.

8. LABORATORY AUDITS

During laboratory audits, emphasis is 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, and intra-laboratory check sample and quality assurance programs, including standards books and corrective actions. No residues laboratory was audited during this audit.

Microbiology laboratory audit 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 two microbiology laboratories were audited:

- Government laboratory "Animal Diseases and Food Safety Research, Microbiology Unit" provides information on international standards and methods to laboratories testing U.S. export products. This laboratory is located in Helsinki.
- Private laboratory "HK RUOKATALO OY" conducts *Salmonella* and generic *E. coli* testing of porcine carcasses at Establishment 18 in Forssa.

The laboratory at Establishment 18 performs testing on samples from Establishments 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.

9. SANITATION CONTROLS

As stated earlier, 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, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

Specific deficiencies are noted on the attached individual establishment reports.

9.1 SSOP

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 two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies in the implementation of SSOP:

- In one establishment, viscera trays in the evisceration room were observed with a buildup of organic material.
- Excessive hair was observed on the ham and belly of two swine carcasses in the coolers.
- The time when the pre-operational sanitation inspection was performed in the cutting room was not recorded as required by the establishment's written program.

9.2 Sanitation Performance Standard

The following deficiencies were observed:

- In one establishment, flaking paint and rust were observed on a wall in the dry storage room.
- 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.
- A metal piece welded to the pork belly belt in the cutting room had uneven and rough welding, creating a potential source of contamination due to the inability to properly clean this product contact surface.

9.3 EC Directive 64/433

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 buildup of organic material.

• A metal piece welded to the pork belly belt in the cutting room had uneven and rough welding, creating a potential source of contamination.

See the attached individual establishment reports for list of 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 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 humane 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 Humane Handling and Humane Slaughter

No deficiencies were observed regarding humane handling or humane slaughter.

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 the both establishments. The following deficiency was observed:

• In one establishment, it was not clear in the HACCP records that verification is conducted for record review or for the direct observation of monitoring for CCP1.

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 measure(s):

• Finland may allow either establishment or government employees, who are fully trained, to take samples applicable to generic *E. coli* testing program.

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.

Testing for generic *E. coli* was properly conducted in the slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

None of the two 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 observed:

• Government inspectors were not palpating the pork tongues at the post mortem 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 residue laboratory was audited during this audit.

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

12.1 EC Directive 96/22

No residue laboratory was audited during this audit.

12.2 EC Directive 96/23

No residue laboratory was audited during this 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 both 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 ISO 6579:2002(E) for *Salmonella*.
- FSIS has granted Finland an equivalence determination allowing the use of methods ISO 6579:1993 and NMKL 71 (dated 1999) for *Salmonella*.

The establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was 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 Supervisory Reviews

During this audit it was found that monthly 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 observed:

• Government inspectors were not palpating the pork tongues at the post mortem 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 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. CLOSING MEETING

A closing meeting was held on May 21, 2007, in Helsinki with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

- Hallingov

The CCA understood and accepted the findings.

Farooq Ahmad, DVM
Senior Program Auditor

15. ATTACHMENTS

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

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE		3. ESTABLISHMENT NO. 4. NAME OF COUNTRY		
HK Ruokatalo Oy Teollisuuskatu 17	5/14/2007		18 Finland		
1comsuuskatu 17	5. NAME OF AUDITOR(S)		R(S)	6. TYPE OF AUDIT	
Forssa 30420	Farooq Ahmad, I		DVM X ON-SITE AUDIT DOC		IT AUDIT
Place an X in the Audit Results block to inc	licate nor	compl	iance with requireme	ents. 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		
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		
Corrective action when the SSOPs have falled 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		
Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		-
 Records documenting implementation and monitoring of the HACCP plan. 			43. Water Supply	d	-
The HACCP plan is signed and dated by the responsible establishment individual. Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			44. Dressing Rooms/Lavatories 45. Equipment and Utensilis		
			46. Sanitary Operations		
18. Monitoring of HACCP plan.			47. Employee Hygiene X		
19. Verification and validation of HACCP plan.		x	48. Condemned Product Control		
20. Corrective action written in HACCP plan.					
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements		
Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		х	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverag	je	
23. Labeling - Product Standards			51. Enforcement		V
24. Labeling - Net Weights			52. Humane Handling		X
25. General Labeling			52. numarie nandling		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Molsture)			53. Animal Identification		
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection		
27. Written Procedures			55. Post Mortem Inspection		x
28. Sample Collection/Analysis			Part G - Other Regul	latory Oversight Requirements	
29. Records					
Salmonella Performance Standards - Basic Requi	rements		56. European Community Din	ectives	X
30. Corrective Actions			57. Monthly Review		
31. Reassessment			58.		
32. Written Assurance			59.		

60. Observation of the Establishment

Date: 5/14/2007 Est #: 18 (HK Ruokatalo Oy [S/P]) (Forssa, Finland)

Slaughter/processing

- 19/22/51 It was not clear in the HACCP records that verification is conducted for record review or for direct observation for CCP1. Immediate corrective actions were taken. [Regulatory references: 9CFR 417.4(a)(2)(ii)(iii) and 417.5(a)(3)]
- 39 Flaking paint and rust were observed on a wall in the dry storage room. The government official assured immediate corrective actions. [9CFR 416.2(b)(2)]
- 47/56 White working clothes and street clothes were hanging together in an employee locker room, causing insanitary conditions. Immediate corrective actions were taken. [9CFR 416.5(b) and EC Directive 64/433, Chapter III]
- 51/55/56 Government inspectors were not palpating the pork tongues at the post mortem station. The government official took immediate correction actions. [EC Directive 64/433, Chapter VI, 24(b)]

61. NAME OF AUDITOR Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

DM 5/31/2007

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	5/10/2007 22		22	Finland		
	5. NAME OF	AUDITO	R(S)	6. TYPE OF AUDIT		
Nurmo 60550	Farooq Ahmad, D		VM	X ON-SITE AUDIT DOCUME	AUDIT DOCUMENT AUDIT	
Place an X in the Audit Results block to inc	dicate nor	compl	iance with requirem	ents. Use O if not applicable).	
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling		Audit Results	
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Records documenting implementation.			34. Species Testing			
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Corrective action when the SSOPs have falled to prevent direct product contamination or adulteration.		х	38. Establishment Grounds and Pest Control			
13. Daily records document item 10, 11 and 12 above.		Х	39. Establishment Construction/Maintenance			
Part B - Hazard Analysis and Critical Control			40. Light			
Point (HACCP) Systems - Basic Requirements 14. Developed and implemented a written HACCP plan.		<u></u>	41. Ventilation			
15. Contents of the HACCP list the food safety hazards,			42. Plumbing and Sewage			
critical control points, critical limits, procedures, corrective ac 16. Records documenting implementation and monitoring of the			43. Water Supply			
HACCP plan.			44. Dressing Rooms/Lavator			
 The HACCP plan is signed and dated by the responsible establishment individual. 			45. Equipment and Utensils		x	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46. Sanitary Operations			
18. Monitoring of HACCP plan.			47. Employee Hygiene			
19. Verification and validation of HACCP plan.			48. Condemned Product Co	ntrol		
20. Corrective action written in HACCP plan.						
21. Reassessed adequacy of the HACCP plan.			Part F - In	spection Requirements		
 Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur. 			49. Government Staffing			
Part C - Economic / Wholesomeness			50. Daily Inspection Coverag	gė		
23. Labeling - Product Standards			51. Enforcement		x	
24. Labeling - Net Weights			52. Humane Handling			
25. General Labeling 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			53. Animal Identification			
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection			
27. Written Procedures			55. Post Mortem Inspection		-	
28. Sample Collection/Analysis			55, Fost with tent inspection			
29. Records			Part G - Other Regul	latory Oversight Requirements		
			56. European Community Din	ectives	X	
Salmonella Performance Standards - Basic Requi	rements					
30. Corrective Actions			57. Monthly Review			
31. Reassessment			58.	·····		
32. Writen Assurance			59.			

60. Observation of the Establishment

Date: 5/10/2007 Est #: 22 (Atria Oyj [S/P]) (Nurmo, Finland)

Slaughter/processing

10/51/56 Viscera trays in the evisceration room were observed with buildups of organic material. The government official assured immediate corrective actions. [Regulatory references: 9CFR 416.4 and 416.13(c) and EC Directive 64/433, Chapter III]

- 12 Excessive hair was observed on the ham and belly areas of two swine carcasses in the coolers. Immediate corrective actions were taken. [9CFR 416.15(b)]
- 13 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. The government official assured immediate corrective actions. [9 CFR 416.16(a)]
- 38 A white powder (in an approximately two-foot-square area) was observed on the floor in the dry storage room. Immediate corrective actions were taken. [9CFR 416.2(a)]
- 45/51/56 A metal piece welded to the pork belly belt in the cutting room had uneven and rough welding, creating a potential source of contamination. The government official assured immediate corrective actions. [9CFR 416.3(a) and EC Directive 64/433, Chapter III(c)]

61. NAME OF AUDITOR Faroog Ahmad, DVM 62. AUDITOR SIGNATURE AND DATE

voy Frank DAY

5/31/2007



September 6, 2007

6388/922/2007

Donald Smart
Director
International Audit Staff
Office of International Affairs
1299 Farnam St.
Suite 300, Landmark Center
Omaha, NE 68102

THE DRAFT AUDIT REPORT FOR FINLAND May 7. - May 21, 2007

Dear Mr. Smart,

Please find enclosed the comments of The Finnish Food Safety Authority on the draft audit report 2007:

3. PROTOCOL

Sixth paragraph, last sentence: FSIS has granted Finland an equivalence determination allowing the use of ISO 6579:2002(E) 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.

6.2 Government Oversight

Second paragraph, first sentence should read: 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 new FSA, since May 2006.

6.2.1 CCA Control Systems

First paragraph, first sentence should read: Department of *Food and Veterinary Control in the FSA has been separated into the units* of Animal Health and Welfare, Food Hygiene, Meat and Fish Hygiene, Product Safety and Marketing and *Food Control and Veterinary Services*, since May 2006.

6.2.2 Ultimate Control And Supervision

First paragraph, first sentence should read: The tasks of the current FSA office include meat inspection in slaughterhouses and approval of the slaughterhouses and connected establishments. Municipal control authorities are responsible for approval of other establishments and meat inspection in small slaughterhouses.

förnamn.efternamn@evira.fi

13.2 Testing for Salmonella

Bullet point one: Please see comment about 3. PROTOCOL.

Yours sincerely,

Eija Läikkö Director, Deputy Meat and Fish Hygiene Unit

Sirpa Kemilä Senior Officer Meat and Fish Hygiene Unit