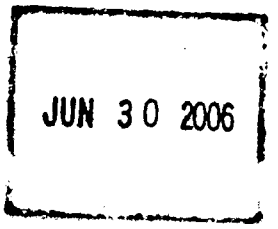
United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250



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

Dear Dr. Maki-Petays:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in Finland from November 9 through November 22, 2005. Comments from Finland have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions about this audit or need additional information, please contact me at 202-720-3781, facsimile 202-690-4040, or email at sally.white@fsis.usda.gov.

Sincerely,

Sally White JP

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Margaret Thursland, Counselor, US Embassy, Stockholm
Hannele Tikkanene, Counselor, Embassy of Finland
Canice Nolan, First Secretary, EU Mission to the US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
James Dever, FAS Area Officer
Bob Macke, Assistant Deputy Administrator, ITP, FAS
Barbara Masters, Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA
Bill James, Deputy Assistant Administrator, OIA
Linda Swacina, Executive Director, FSIA, OIA
Donald Smart, Director, Program Review, OPEER
Clark Danford, Director, IEPS, OIA
Sally White, Director, IES, OIA
Mary Stanley, Director, IID, OIA
Barbara McNiff, FSIS Codex Programs Staff, OIA
Ghias Mughal, IES, OIA
Amy Winton, State Department
Country File

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FINAL

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

November 9 through November 22, 2005

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [the National Food Agency (NFA)]
E. coli	*Escherichia coli*
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 Systems
SVO	Senior Veterinary Officer
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Finland from November 9 through November 22, 2005.

An opening meeting was held on November 9, 2005, in Helsinki with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of Finland's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the National Food Agency (NFA).

2. OBJECTIVE OF THE AUDIT

This was an enforcement 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. The findings would determine whether Finland could continue exporting meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two local inspection offices, one government residue laboratory, four microbiology laboratories performing analytical testing on U.S. eligible product, three slaughter/processing establishments and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	1	Helsinki
	Local	2	Establishment level
Laboratories		5	Four microbiology & one residue testing laboratory.
Meat Slaughter and Processing Establishments		3	
Cold Storage Facilities		1	

3. PROTOCOL

This enforcement audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to four establishments: three slaughter/processing establishments and one cold storage facility. The third part involved visits to four microbiology laboratories (two government and two privately owned laboratories) 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), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs, (4) residue controls, and (5) enforcement controls. Finland's inspection system was assessed by evaluating these five risk areas.

During all establishment visits, the auditors 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 opening meeting, the lead 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 auditors 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 auditors 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* species.

Third, the auditors would audit against any equivalence determinations that have been made by FSIS for Finland under provisions of the Sanitary/Phytosanitary Agreement. Finland has several alternate procedures that have been recognized as equivalent: For generic *E. coli* testing, government employees select the samples; for *Salmonella* testing of raw product, establishments take samples, private laboratories analyze samples, an alterative testing strategy is used, and different sampling tools, sampling techniques, analytical methods, and location and size of sample sites can be used. In addition, in lieu of generic *E. coli* testing of raw product, Finland can test raw product for *Enteriobacteriaceae* and Total Viable Count.

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 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 last three FSIS audits of Finland's meat inspection system (2003-2005) indicated serious non-compliance with FSIS inspection requirements and included:

- Direct product contamination/potential for product contamination.
- Inadequate verification of HACCP plans and implementation of SSOP.
- Insufficient government oversight and enforcement of FSIS inspection requirements.

In addition, the following concerns were identified during these three audits:

<u>February/March 2005</u>

- One slaughter/processing establishment was issued an NOID for various deficiencies. Most notable were direct product contamination and dripping/beaded condensation over product areas.
- Four establishments were cited for inadequate enforcement of FSIS inspection requirements, such as HACCP, SSOP and SPS requirements.
- Some sanitation deficiencies previously observed and documented, (e.g., direct product contamination) remained uncorrected from the previous audit.
- Veterinarians assigned to all FSIS-certified establishments appeared to lack adequate knowledge of FSIS requirements.

<u>January 2004</u>

- One of five audited establishments was issued an NOID for SSOP/SPS deficiencies. In this establishment, direct product contamination was observed and fat and meat particles were observed on white tubs ready for use. One unclean meat hook was contacting edible product and inedible and edible containers were being used for edible product.

- In three establishments, SSOP records did not include any corrective actions taken by establishments.
- In two establishments, there was inadequate enforcement of FSIS inspection requirements.

March 2003

- In two establishments, maintenance and cleaning of overhead structures above products had been neglected.
- In one establishment, cross-contamination was observed in one area.

6. MAIN FINDINGS

6.1 Legislation

The NFA is currently in the process of clarifying and issuing new legislation and 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 Operations— is being incorporated into new Finnish legislation.

6.2 Government Oversight

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. In May 2006, the NFA will become part of the Food Safety Authority (FSA). The provincial veterinarians, who are part of the Ministry of the 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 for establishments certified for export to the United States.

The NFA and other staffs and some functions of the Department of Food and Health and Animal Health and Welfare will merge into the new FSA. All of these entities will report to a Director General. The new FSA will consist of two Departments, the Department for Control of Primary Production and the Department for Control of Veterinary Medicine and Food. Additionally, the FSA will have separate units for communications, risk assessment, and internal review.

The NFA will be part of the Veterinary Medicine and Food Control Department. The FSA will be responsible for uniform implementation of field to table controls employing risk assessment procedures.

6.2.1 CCA Control Systems

The Department of Veterinary Medicine and Food Control in the FSA will be separated into the Departments of Animal Health and Welfare, Food Hygiene, Meat and Fish Hygiene,

Product Safety and Marketing, and Direction of Food Control and Veterinary Medicine. The meat inspection personnel will be part of this new Department.

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

6.2.2 Ultimate Control and Supervision

The tasks of the current NFA includes meat inspection in slaughterhouses and other establishments, approval of the slaughterhouses and other establishments, national testing programs for residues and for *Salmonella* species in meat, and controls for meat exports outside the European Union. The in-plant inspection personnel are now supervised by the NFA Senior Veterinary Officers stationed at the NFA Headquarters in Helsinki.

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

Since streamlining of the role of the SVO in September 2005, two monthly evaluations of the performances of the in-plant inspection personnel have been performed and concerns discussed with the in-plant inspection personnel.

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. Some have been implemented while some others are in the process of being finalized.

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 June 2005, a one-day training course was organized by the NFA to provide additional training on U.S.-export issues including HACCP, SSOP and SPS requirements to both inspection personnel and establishment personnel. This course was presented by an outside consulting organization and included both classroom and hands-on training.

In September of 2005, a one-week training course was organized by the NFA to provide additional training in HACCP, SSOP and SPS requirements and verification for inspection personnel and establishment personnel. This course was presented by an outside consulting organization and included both classroom and hands-on training.

These training programs have led to improvements in knowledge of the inspectors. However, the NFA needs to continue training in HACCP and SSOP requirements since deficiencies in these areas were still identified in three of the audited establishments.

6.2.4 Authority and Responsibility to Enforce the Laws

Although the NFA has the authority and the responsibility to enforce U.S. and E.C. requirements, in three of the four establishments audited inspectors were not fully enforcing FSIS requirements relating to HACCP, SSOP and microbial testing programs.

6.2.5 Adequate Administrative and Technical Support

The CCA is not providing direct oversight over the laboratories conducting testing of meat products destined for the United States. See Section 13.2 of this report.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents at the headquarters and in-plant inspection offices at the audited establishments. Discussions were held on the Finnish Corrective Action Plan 2005, which was sent to FSIS in September 2005. All corrective actions taken by the NFA were verified through the document review.

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, and
- 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 of Regional and Local Inspection Sites

No provincial inspection offices were visited since provincial veterinarians are no longer involved in inspection oversight. Inspection offices at two establishments were audited. Monthly supervisory reviews in September and October 2005 had been performed by the SVOs and now included evaluations of inspection personnel. These reviews showed improvements in the understanding and implementation of the FSIS inspection requirements.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited three slaughter and processing establishments and one cold storage facility. None of the four establishments was delisted by the NFA. One establishment received a NOID from the NFA because of HACCP and SSOP implementation deficiencies. This establishment may retain its certification for export to the United States provided that the establishment corrects all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

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.

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 four microbiology laboratories were visited:

- EELA-Helsinki - provides technical guidance to laboratories testing U.S. export products.
- EELA-Kuopio - conducts specific serological examinations and other epidemiological sub-typing of *Salmonella* spp. isolated and identified by U.S. export testing laboratories.
- Two private laboratories conduct *Salmonella* and generic *E. coli* testing of porcine carcasses.
    - Establishment 18 laboratory at Forssa.
    - Establishment 22 laboratory at Nurmo.

The Establishment 18 laboratory performs testing on samples from Establishments 18 and 85.

Findings from these laboratories are discussed in Section 11.3 (Testing for Generic *E. coli*), Section 12 (Residue Controls), and Section 13.2 (Testing for *Salmonella* species) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focus 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 establishments, and as noted below, Finland's inspection system needs to strengthen its in SSOP programs, and in some aspects of facility and equipment sanitation to prevent of actual or potential instances of product cross-contamination and to improve oversight on personal hygiene practices, and good product handling and storage practices.

Finland's inspection system had controls in place for lighting, ventilation, plumbing and sewage, water supply, dressing rooms/lavatories, equipment and utensils, sanitary operations, employee hygiene, and condemned product control.

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 United States' domestic inspection program. The SSOP in all four establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies in the implementation of SSOPs.

In two establishments, the following deficiencies were observed concerning implementation of SSOP requirements:

- Product contamination was observed from rail grease.
- Cross contamination of product was identified in the cut up area when the unclean feet of a hog carcass came into contact with the conveyor belt used for transporting the carcasses.
- Product (meat trim) was overhanging from the borders of their storage bins onto a surface which was not suitable for product contact.

In one establishment, the following deficiency was observed in record keeping:

- Some entries on establishment records were not completed in association with sanitation deficiencies, rendering it impossible to determine whether contamination of product had taken place.

9.2 Sanitation Performance Standards

In one establishment, boxes to be used for edible product were stored unprotected with some boxes covered by a thin layer of dust.

9.3 EC Directive 64/433

In three of the four establishments, the sanitation provisions of EC Directive 64/433 were effectively implemented. See the attached individual establishment reports for deficiencies.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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 auditors 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 auditors 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 identified regarding humane handling or humane slaughter.

11.2 HACCP Implementation

HACCP deficiencies were identified in three establishments.

- At three establishments, portions of the HACCP records did not include a complete set of time, date, and initials (or signatures) of the person making each entry.
- At one of these establishments, critical control points addressing carcass temperature and zero tolerance, frequency of monitoring of the carcass temperature, and frequency of verification activities, and records review were not clearly defined. ???????

11.3 Testing for Generic *E. coli*

Three of four establishments were required to test for generic *E. coli*. No deficiencies were observed.

11.4 Testing for *Listeria monocytogenes*

None of the four establishments was producing ready-to-eat products for export to the United States. Accordingly, FSIS requirements for testing for *Listeria monocytogenes* do not apply.

11.5 EC Directive 64/433

In all three slaughter and processing establishments, the provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors reviewed was Residue Controls.

The government National Veterinary and Food Research Institute laboratory in Helsinki was audited. No deficiencies were observed

12.1 EC Directive 96/22

In the National Veterinary and Food Research Institute laboratory in Helsinki, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Veterinary and Food Research Institute laboratory in Helsinki, the provisions of EC Directive 96/23 were effectively implemented.

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* species.

13.1 Daily Inspection

Inspection was being conducted daily as required.

13.2 Testing for *Salmonella* in Raw Product

Three of four establishments were required to test for *Salmonella* in raw product. No deficiencies were observed in the establishments.

However, two private and two government laboratories that conduct Salmonella testing of product intended for U.S. export were audited and the following deficiencies were noted:

- The laboratory in establishment 18 in Forssa performs testing for *Salmonella* samples for establishments 18 and 85. This laboratory does not use positive and negative controls with each group of U.S. export samples.

- The laboratory in establishment 22 in Nurmo also does not use positive and negative controls with each group of US export samples. It also does not perform biochemical confirmation on-site. A review of records indicated that, until the day prior to the audit, an excessive temperature tolerance had been allowed for incubation of RVS Broth, although the actual instance of excessive temperature was not found in the records. If, in the opinion of the laboratory, method tolerance ranges cannot be reliably achieved, analyses cannot be regarded as valid.

- The laboratory in establishment 18 does not annotate thermometer error temperature records and working thermometers and balances are not calibrated annually. For each prepared batch of media, autoclave records were not clearly traceable to other media preparation records.

- The CCA is not providing direct oversight over the laboratories conducting testing of meat products destined for the United States. This function is 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 the specific needs of the U.S. export testing program.

13.3 Species Verification

At the time of this audit, Finland was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

Since September 2005, monthly reviews in all establishments certified for export to the United States are being performed by an SVO from the NFA headquarters office in Helsinki. Documentation of findings and follow-up on corrective actions shows improvement. However, some of the documentation was not clear.

13.5 Inspection System Controls

During this audit, deficiencies in enforcement controls of the NFA relating to FSIS requirements were identified in three of the four establishments and two private laboratories. The NFA is in the process of clarifying and issuing new guidelines to strengthen government oversight of HACCP and SSOP requirements. NFA inspection officials advised the auditors that these guidelines/legislation are expected to be finalized and disseminated to inspection personnel by the spring of 2006.

The CCA had controls 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.

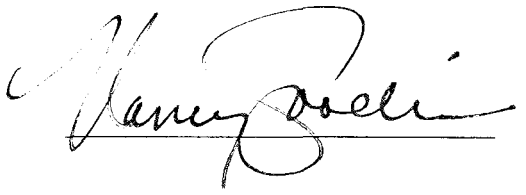
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on November 22, 2005, in Helsinki with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

for Dr. M. Ghias Mughal
Lead Auditor



15. ATTACHMENTS

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

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
Pakastamo Oy Itainen Valkoisenlahteentie 21 01260 Vantaa	11/18/05	6475	Finland

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT
Dr. Alexander L. Lauro	[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	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

Est.#: 6475
City and Country: Vantaa, Finland
Date: 11-18-05

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

61. NAME OF AUDITOR

Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE

1 5/

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 30420 Forssa	11-11-05	18	Finland

5. NAME OF AUDITOR(S): Dr. Alexander L. Lauro

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
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9. Signed and dated SSOP, by on-site or overall authority.	
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12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
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22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
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31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Est.#: 18
City and Country: Forssa, Finland
Date: 11-11-05

22. / 51. The records associated with the monitoring of the critical control point for carcass chilling (CCP #2) were incomplete. Only one line in a series of five entries associated with the monitoring of carcasses included the time of monitoring, as well as the initials of the employee responsible for completing the record. The remaining four entries from this series included only carcass temperature. [9 CFR 417.5(b)]

10. / 51. Rail grease, with a dimension of 1cm x 3cm, was identified on the outside portion (i.e. cutaneous surface) of a section of pork ribs. In addition, the rails of the cooler from which the product was being moved presented a thick build-up of flaking grease on their surface. The CCA notified the establishment of the noncompliance, and corrective actions were immediately implemented. Further investigation by the CCA revealed that the build-up of grease was documented by the establishment on their sanitation records, which also indicated that these rails were scheduled for cleaning post-production. [9 CFR 416.13]

27. / 28. / 29. FSIS has now determined the use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU exporting countries.

61. NAME OF AUDITOR

Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE

151

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 Oy (Nurmo Production) Nurmo	11-17-05	22	Finland

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT
Dr. Alexander L. Lauro	[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 SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
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.	X
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est.#: 22
City and Country: Nurmo, Finland
Date: 11-17-05

10. / 51. On two instances, product (meat trim) was identified overhanging from the borders of their storage bins onto a surface which was not suitable for product contact. In the first case, product was seen touching the rollers of a conveyor track, while in the second case product was seen touching the floor of a production stand. The establishment was notified of the noncompliance, and initiated proper corrective actions. During the course of the audit, no operational SSOP noncompliances were identified in either the establishment or inspection records within approximately the last two months of operation. [9 CFR 416.4, 416.13 (c)] [Council Directive 64/433/EEC, Annex I, Chapter III, section 5]

10. / 51. While observing the cut-up area, cross-contamination of product was identified when the unclean feet of a hog carcass came into contact with the conveyor belt used for transporting these carcasses. The feet of this carcass contained burned hair, and other dark tarry material, both on the outer surface and within the interdigital space. Many of the remaining carcasses waiting to undergo this production phase presented feet of a similar nature. The establishment was notified of the problem, and immediately took proper corrective actions. [9 CFR 416.4, 416.13(c)] [Council Directive 64/433/EEC, Annex I, Chapter III, section (c)]

27. / 28. / 29. FSIS has now determined the use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU exporting countries.

13. / 51. The records documenting the implementation of establishment's sanitation program contain both SPS and SSOP elements, and distinction between the two categories is indicated by a specific entry on the form. The review of these records revealed that in some cases this entry was not completed in association with sanitation deficiencies, thereby rendering it impossible to determine whether contamination of product had taken place. [9 CFR 416.16(a)]

46. One palette of unfolded boxes in the storage room was not maintained in a manner sufficient to prevent the creation of insanitary conditions, or the possible adulteration of product. These boxes were stored uncovered, with their interior (after folding) surface face up, and the surface of some of these boxes was covered with a thin layer of dust. [9 CFR 416.4] [Council Directive 64/433/EEC, Annex I, Chapter III]

Several noncompliances were identified concerning the establishment's HACCP plan addressing carcass chilling:

- 15. /51. The critical limit was not clearly defined as it was stated to be 7° C, yet it was unclear whether this referred to surface temperature or internal temperature. Daily monitoring performed by the establishment measured the internal temperature, but the corrective actions described in the HACCP plan used to demonstrate that the CCP was under control made reference to surface temperature. [9 CFR 417.2 (c)(3)]
- 15. / 51. The monitoring frequency was not clearly defined. [9 CFR 417.2 (c)(4)]
- 15. / 51. The frequency at which the verification procedures addressing the observation of monitoring and records review were not clearly defined. [9 CFR 417.2 (c)(7)]

Several noncompliances were identified concerning the establishment's HACCP addressing the control of visible feces, ingesta, and milk on carcasses and carcass portions:

- 15. / 51. The critical limit was not clearly defined. The portion of the plan describing the CCP simply stated the "the critical limit is zero" without mentioning what was being controlled (i.e. no mention of feces, ingesta, or milk), while the portion of the plan made reference to controlling feces, as well as "other contamination".
- 16. / 51. In association with the first bullet of this section, if the plant had determined "other contamination" as part of this CCP, the HACCP records did not clearly document control of this hazard. [9 CFR 417.5 (a)(3)]
- 16. / 51. The verification records documenting the observation of monitoring of this CCP did not include the time at which entry occurred. [9 CFR 417.5 (b)]

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
1 51

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 Mellila Finland	11-14-05	85	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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.	X
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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Est.#: 85
City and Country: Mellila, Finland
Date: 11/14/2005

13. / 51. A review of the establishment's SSOP records indicated improper documentation of corrective actions taken in response to contamination of product, or product-contact surfaces. In several instances, the disposition of product was not documented as part of the establishment's corrective actions taken in response to SSOP issues (9 CFR 416.16(a)).

15. / 51. The establishment determined the critical limit (CL) associated with carcass chilling to be 7° C within 20 hours, yet the records associated with the monitoring of this CCP did not include the time element. Without an indication of time on the records, it is impossible to determine whether the CCP was met. [9 CFR 417.5(a)(3)]

22. / 51. The records associated with the monitoring of the critical control point for visible feces, ingesta, and milk (CCP #1B: "zero tolerance") did not include the time at which each entry occurred. [9 CFR 417.5(b)]

27. / 28. / 29. FSIS has now determined the use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU exporting countries.

61. NAME OF AUDITOR

Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE

11/14/05

ELINTARVIKEVIRASTO
Livsmedelsverket National Food Agency

April 03, 2006 3151/43/05

Sally White, Director
USDA, FSIS, OIA, IES
Rm. 2137-S
1400 Independence Ave., SW
Washington, DC 20250

Dear Dr. White

Ref: Your letter, February 03, 2006

Subject: **AUDIT REPORT FOR FINLAND, November 9. – November 22, 2005**

The National Food Agency (NFA) has the following comments as regards audit report, 2005:

6. Main findings

6.2.3. Second and third paragraph:
In June 2005, a one-day training on U.S.-export issues, HACCP, SSOP and SPS was provided to establishments certified for export to the United States and the inspection veterinarians associated with the establishments. Half of the training was held for all participants and focused on U.S. -requirements. Half of the training was held only for the inspection veterinarians and focused on verification.

In September 2005, a one week long training course was organized by the NFA to provide additional training in HACCP, SSOP and SPS requirements and verification. The course was presented by an outside consulting organization and included both the class room and hands-on training. Both the establishments exporting to the United States and the NFA personnel participated. One of the two class room days was held only for the NFA personnel and focused on verification. The other class room day was open to all participants, focusing on requirements.

11. Salughter/prosessing controls

11.2.
Bullet point one: Please see comment about Requirement 417.5 b) below.
Bullet point two: Please see comment about Requirement 417.5 b) below.
Bullet point three: Comment about frequency of monitoring and verification is correct concerning the HACCP plan of the cutting plant. It is however unclear to us, if the text in the draft report is also referring to the HACCP plan of the slaughterhouse (there is "zero tolerance" mentioned in the text). The HACCP plan of the slaughterhouse contained the relevant information about both the monitoring and verification frequency.

11.5.
The comment remains unclear to us. Furthermore, we do not find any comment about post mortem inspection in the attached individual establishment reports, as mentioned in the text of the draft report.

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15. Attachments

- Establishment 18:

22./51.
Please see comment about Requirement 417.5 b) below. Furthermore, the CCP of the cutting plant is not monitored by measuring the temperature of the carcasses at this establishment, although the temperatures of the carcasses taken to the cutting plant are measured due to a specific requirement in our national legislation. Establishment 18 monitors the CCP of the cutting plant by measuring temperatures of cut meat ready for packaging.

- Establishment 22:

10./51./56.
The comment remains unclear to us concerning the lack of identification of SSOP non-compliances in inspection records within approximately the last two months of operation counted from the USDA audit date. The official daily records have been audited and it has been ascertained by us, that there are SSOP-remarks written from the time period mentioned in the text of the draft report.

Establishment's HACCP plan addressing the control of visible faeces, ingesta and milk on carcasses and carcass portions:
15/51. and 16/51.
Bullet points one and two: The reference to "other contamination" was in hazard analysis. "Other contamination" would more correctly be translated as "other kinds of factors to be trimmed" in final trimming rather that "contamination". We consider it adequate to describe all the events of final trimming in hazard analysis, taking all potential hazards into account before making the decision about what and why actually can be considered as the CCP. We have approved the CCP to be a certain part of a working phase (all the final trimming is actually happening in one place and done by the same person), and have not required the establishments to have a factitious final trimming working phase for trimming faecal, ingesta and milk apart from the rest of the working phase.

16./51.
Bullet point three: the comment remains unclear to us. The verification records documenting the observation of monitoring included both the time for starting and ending the verification in a special column of the form.

- Establishment 85:

13./51.
The comment remains unclear to us. In our notes we find two SSOP-matters discussed about during the audit of the establishment 85:
- A case, where the inspection veterinarian had noticed just before the end of the working day, that the person performing both the bunging and cutting off the tails did not wash his hands with soap between these two working phases, but used only water. The inspection veterinarian had notified the foreman of the slaughterhouse about the remark by writing the non-compliance on the form of working hygiene for that day and ordered the establishment to dispose all the tails from that day's slaughter. The foreman had documented following corrective actions on the same form next day: schooled the person in question immediately. All the tails have been disposed.
- A case, where the foreman had noticed that the person splitting the carcasses could change the order of the different working phases so, that the saw could be sterilized for a longer period. The foreman schooled the person to perform the different working phases in an optimal order and documented the event on the establishment record of working hygiene for that day. The foreman

had also documented that the person had been sterilizing the splitting saw properly but not optimally already. It was clearly understandable in the text, although not written specifically, that the product was not adulterated. Therefore, we consider the documentation to be correct.

22./51.
Please see comment about Requirement 417.5 b) below.

Requirement 417.5 b), Code of Federal Regulations
There were discussions about the requirement 417.5 b) "Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialled by the establishment employee making the entry." In the draft report, there are several non-compliances to this requirement mentioned, all of them about the documentation of date, time and initials for each entry. Therefore, we would like to explain how the system has been in Finland, accepted by us, and ask your opinion to whether the practise is acceptable or not.
All the slaughterhouses exporting meat to United States have chosen the same CCP, final trimming, and monitoring it by examining if the carcasses are contaminated with faecal, ingesta or milk after the final trimming. The frequency of monitoring and the amount of carcasses monitored at a time varies from one establishment to another. All the establishments monitor the chosen amount of carcasses so, that the carcasses are coming in consecutive order, next to each other, to the monitoring place. One monitoring event takes at highest some minutes of time. After the monitoring, the one responsible for it documents the numbers of the examined carcasses, the remarks about whether the limits were met, and the date, time and initials for the monitoring event on the monitoring form. Therefore, we have considered the documentation to be as one entry in total, and not as one entry per carcass.
The cutting plant in establishment number 18 has chosen to monitor 5 pieces of cut meat during one monitoring event. The monitoring is performed in connection with weighing. There are thus 5 measurements of temperature one after another. One monitoring event takes at highest some minutes of time. The one responsible for monitoring documents the type of the product (piece), the temperature, and the date, time and initials for the monitoring event on the monitoring form. We have considered the documentation to be as one entry in total, and not as one entry per meat piece.

Yours sincerely,

Osmo Mäki-Petäys
Director
Meat and Fish Hygiene Unit

Tiina Läikkö
Senior Officer
Meat and Fish Hygiene Unit