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

AUG 18 2005

Dr. Osmo Maki-Petays
Head of Meat Hygene Unit
National Veterinary & Food Research Institute
Hameentie 57
Fin-00231 Helsinki, Finland

Dear Dr. Maki-Petays:

The Food Safety and Inspection Service conducted an on-site audit of Finland's meat inspection system February 23 through March 11, 2005. Comments from Finland have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

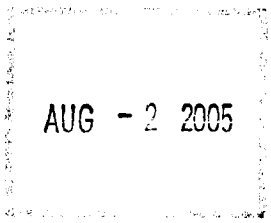
Sally White JD

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:
Margaret "Peg" Thursland, Counselor, American Embassy, Stockholm
Hannele Tikkanene, Counselor, Embassy of Finland
Canice Nolan, EU Mission to the US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
Scott Bleggi, FAS Area Officer
Bob Macke, Assistant Deputy Administrator, International Trade Policy (ITP), FAS
Amy Winton, State Department
Barbara Masters, Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
Bill James, Deputy Assistant Administrator, OIA, FSIS
Linda Swacina, Executive Director, FSIA, OIA
Donald Smart, Director, Program Review, OPEER, FSIS
Clark Danford, Director, IEPS, OIA
Sally White, Director, IES, OIA
Mary Stanley, Director, IID, OIA
Armia Tawadrous, FSIS Codex Staff, OIA
Shannon McMurtrey, IES, OIA
Country File

FINAL



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

February 23 through March 11, 2005

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 [the National Food Agency (NFA)]
E. coli	*Escherichia coli*
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
PVO	Provincial Veterinary Officer
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Finland from February 23 through March 11, 2005.

An opening meeting was held on February 23, 2005, in Helsinki with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itinerary, 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 a routine annual 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.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three provincial inspection offices, one government-owned residue laboratory and one private microbiology laboratory performing analytical testing on United States-eligible product, three slaughter and processing establishments, one slaughter establishment, and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	1	Helsinki
	Provincial	3	Forssa, Turku, and Nurmo
	Local	4	Establishment level
Laboratories		2	Helsinki, Pietarsaari
Meat Slaughter and Processing Establishments		4	
Cold Storage Facilities		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to five establishments: three slaughter and processing establishments, one slaughter establishment and one cold storage facility. The third part involved visits to one government owned and operated residue laboratory and one private microbiology laboratory. The National Veterinary and Food Research Institute laboratory in Helsinki and Oy, Snellman Laboratory in Pietarsaari were

conducting, respectively, analyses of field samples for residues and microbiology for the establishments certified to export product to the U.S.

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 on-site 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 auditors 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. Alternate procedures that have been recognized as equivalent: Finland may allow either establishment or government employees, who are fully trained, to take samples applicable to generic *E. coli* and *Salmonella* species testing programs.

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 two audits of Finland's inspection system have shown several problems. All of the deficiencies identified in March 2003 had been corrected by the audit in January 2004. The following deficiencies were identified:

- In one establishment, cross-contamination was observed between a carcass that was railed out and another carcass that had fallen on the floor.

- In two establishments, maintenance and cleaning of over-product structures had been neglected to varying degrees in several production areas, although no direct product contamination resulting from the neglect was observed during the audit

- In one establishment, general housekeeping in the chemical storage area had been neglected.

During the audit conducted by FSIS in January 2004, the following deficiencies were identified:

- In one establishment, fat and meat particles were observed on white tubs that were ready to use for edible product.

- In one establishment, an unclean hook was contacting edible product.

- In three establishments, the SSOP records did not include adequate descriptions of deficiencies found and the corrective actions taken.

- The provisions of EC Directive 64/433 were effectively implemented in two establishments. In the other three establishments, deficiencies were identified.

- In one establishment, containers designated for edible product were used for inedible product.

- In two establishments, overhead structures were observed with fat residue and meat scraps.

- In one establishment, condensation was noted on the cooling system in the cooler.

- In one establishment, a roll of plastic for edible product was contacting the floor and plastic for packaging was stored in an inedible-designated container.

- In two establishments, calibration of equipment for monitoring critical limits was not clearly defined in the written HACCP plan.

- In one establishment, the written descriptions of monitoring and verification procedures were not clear. Both were performed, but records did not reflect the correct terminology.

- Two of five establishments audited had inadequate enforcement of U.S. requirements in January 2004.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directives, determined to be equivalent under the VEA, had been transposed into Finland's legislation.

6.2 Government Oversight

NFA has the organizational structure and staffing to ensure uniform implementation of U.S. requirements. It is responsible for directing, planning, and developing food control in Finland and for conducting control. Activities cover the control of all foodstuffs from farm to table. NFA guides the municipal food control authorities, provincial governments, and the National Board of Customs, which perform the practical control. NFA is subordinate to the Ministry of Agriculture and Forestry.

6.2.1 CCA Control Systems

NFA is divided into five units: the Meat and Fish Hygiene Unit, the Milk and Egg Hygiene Unit, the Health Protection Unit, the Food Control Unit, and the Administrative Unit. The Meat and Fish Hygiene Unit is responsible for guidance and direction of tasks under the relevant hygiene acts. This unit is also responsible for some tasks under the Act on the Implementation of the Common Agricultural Policy. The unit develops the uniformity and efficiency of food control in its own area. The meat inspection personnel (approximately 100) belong to this Unit. NFA cooperates closely with the National Veterinary and Food Research Institute, and the Plant Production Inspection Centre.

The Ministry of Agriculture and Forestry transposes all relevant European Union legislation into Finnish law.

Mainland Finland is divided into five Provinces. Two of the establishments certified for U.S.-export are located in the Province of Western Finland and the other three in the Province of Southern Finland. This audit included a visit to three Provincial Veterinary Offices in the Province of Southern Finland.

6.2.2 Ultimate Control And Supervision

The tasks of NFA include meat inspection and control 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 supervised both by the NFA Senior Veterinary Officers (stationed in Helsinki) and by the Provincial Veterinary Officers (PVOs), who perform the monthly internal reviews of the establishments certified as eligible to produce products for U.S. export. However, monthly supervisory reviews include only limited evaluation of inspection personnel. Under the current system, all issues that may arise regarding animal health and welfare are expected to be channeled through the PVOs. The PVOs carry the responsibility to evaluate and report on the performance of the in-plant inspection personnel and export procedures. The PVOs, in turn, are also supervised by the NFA Senior Veterinary Officers in Helsinki.

The PVOs discuss their routine evaluation of the performances of the in-plant inspection personnel during the internal reviews. If they have any concerns, they discuss this with their supervisors after the audit is completed.

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

The European Commission's regulations regarding movement, identification, and traceability of animals are enforced in Finland.

The national residue testing program is jointly developed, implemented, and applied by (1) the NFA, (2) the National Veterinary and Food Research Institute, and (3) the Ministry of Agriculture and Forestry.

6.2.3 Assignment of Competent, Qualified Inspectors

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 then 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.

No part-time or full-time government employees are allowed to perform private, establishment-paid tasks at an establishment in which they perform official duties. Private-practicing veterinarians may be hired as temporary or part-time government employees in establishments certified for U.S. export.

The NFA charges the establishments monthly for inspection services, according to the applicable European Union Directive, which has been transposed into Finnish legislation. The NFA pays the field inspection personnel directly.

The NFA needs to continue improving its knowledge of the FSIS inspection requirements including HACCP and SSOP.

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, four of five establishments audited had inadequate enforcement of U.S. requirements.

6.2.5 Adequate Administrative and Technical Support

The NFA has adequate administrative and technical support to operate Finland's inspection system and has the resources and ability to support a third-party audit. The NFA is responsible for hiring veterinarians and other inspection personnel and determines the allocation of personnel to the establishments.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents at the headquarters, provincial, and in-plant inspection offices at the audited establishments. The records reviews focused primarily 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.

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

6.3.1 Audits of Regional and Local Inspection Sites

The provincial inspection offices in Turku, Forssa and Nurmo were audited to gain insight into the oversight of establishment-level inspection controls. The monthly supervisory reviews included only limited evaluation of inspection personnel. Additional training of NFA inspection personnel for U.S. regulatory requirements was needed.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited three slaughter and cutting establishments, one slaughter establishment, and one cold storage facility. None of the five establishments was delisted by Finland's Inspection Service as a result of failure to meet FSIS requirements. One establishment received a Notice of Intent to Delist (NOID) from the Finish Inspection Service because of SSOP implementation deficiencies. This establishment may retain its certification for export to the United States provided that the management corrects all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

8. RESIDUE AND MICROBIOLOGY 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 audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs. If private laboratories are 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 laboratories were audited:

The government-owned and -operated National Veterinary and Food Research Institute laboratory in Helsinki is the reference laboratory for residue testing.

The private micro Laboratory Oy, Snellman Laboratory in Pietarsaari conducts analyses of field samples for microbiology for the establishments certified to export product to the U.S.

The findings in these laboratories will be 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 auditors reviewed was Sanitation Controls.

Based on the on-site audits of 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 practices, and good product handling and storage practices.

In addition, and except as noted below, Finland inspection system had controls in place for light, 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 U.S. 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 three establishments, the implementation of SSOP including monitoring of implementation was deficient.

- In three establishments, the daily records documenting SSOP deficiencies were not properly maintained.

Sanitation Performance Standard

- In one establishment, containers designated for edible product were used for inedible product, or were not properly handled.

- In two establishments, conveyor belts in the boning room were in need of repair.

- In one establishment, lights were not functioning in a significant portion of the carcass cooler. This rendered it difficult to assess the sanitary state of this area, as well as that of the carcasses present.

9.2 EC Directive 64/433

In two establishments, the provisions of EC Directive 64/433 were effectively implemented. In the other three establishments, deficiencies were identified; the specific deficiencies are noted in the attached individual establishment reports.

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

- In one establishment, the monitoring procedure and the following corrective action written in the HACCP plan was not being followed. The establishment's critical control point (CCP) was based on internal temperature, but in actuality surface temperature was being measured.

11.3 Testing for Generic *E. coli*

No deficiencies were identified regarding the testing programs for generic *E. coli.*

11.4 Testing for *Listeria monocytogenes*

None of the five establishments was 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 effectively implemented.

12. RESIDUE CONTROLS

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

The government owned and operated National Veterinary and Food Research Institute laboratory in Helsinki was audited. The following observations were made:

- The method implemented for species verification testing was for cooked product. Finland is exporting only raw product to the U.S.A.

- Turnaround times for heavy metals and hormones were sometimes as long as two months.

12.1 FSIS Requirements

At the time of this audit, four slaughter establishments and one cold-storage facility were certified for U.S. export.

12.2 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 in Establishments

Inspection was being conducted daily, and was well-documented, in all five establishments.

13.2 Testing for *Salmonella* Species

No deficiencies were identified regarding the testing programs for *Salmonella* species.

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

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed. However, the monthly supervisory reviews did not include adequate evaluation of inspection personnel.

13.5 Inspection System Controls

The CCA had controls in place for prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

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.

- Four of five establishments audited had inadequate enforcement of U.S. requirements.

14. CLOSING MEETING

A closing meeting was held on March 11, 2005 in Helsinki with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditors.

The CCA understood and accepted the findings.

Dr. Oto Urban
Senior Program Auditor

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Individual Foreign Laboratory 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 Oyj Teollisuuskatu 17 30420 Forssa Finland	3-2-2005	18	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Finland, 03-02-05 Continuation Est.18

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, "preventive measures" where not documented as part of the establishment's corrective actions taken in response to SSOP issues (9 CFR 416.16(a); 416.17).

40. Lights were not functioning in a significant portion of the carcass cooler. This rendered it difficult to assess the sanitary state of this area, as well as that of the carcasses present (9 CFR 416.2 (c), EC Directive 64/433/EEC, Annex I, Chapter 1, section (o))

55/56/51. Viscera inspectors did not palpate the portal lymph nodes (USA), and liver (EU). In the U.S.A., palpation of the portal lymph nodes is considered an integral step in performing a careful post-mortem inspection of swine (9 CFR 310.1(a)). EU legislation calls for the palpation of the liver during post-mortem inspection of these carcasses (EC Dir 64/433, Annex I, Chapter VI, 24(b)).

45/51/56 White containers, designated for edible product, were being used for inedible product in the primal cut area. The proper corrective action was observed during the audit (9 CFR 416.3, EC Dir. 64/433, Annex I, Chapter II, section (4)).

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE
Oto Urban 3/24/05

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, P.O. Box 900, 600 60 Finland	02 – 25 - 05	22	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
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	X
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Finland, 2-25-05, continuation Est.22

10 Grease was observed on edible product and product contact area (bin of hearts). Affected product was immediately disposed of. Establishment officials were not able to identify the source of contamination at the time of the audit. This deficiency was scheduled for correction (416.13).

13/51 The establishment's operational sanitation records were designed to document both SPS and SSOP issues, but were determined inadequate in their completion as descriptions of the deficiencies did not indicate whether product was involved. This deficiency results in the inability for the establishment to adequately document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken (9 CFR 416.16; 416.17).

45/51/56 Several conveyor belts were observed to be in poor condition with deep cuts at the food-contact surfaces in the de-boning room (416.3a) (EC Directive 64/433, Chapter III, section c.). This deficiency was identified and recorded by the inspection service during the monthly supervisory review but not corrected by the establishment at the time. Corrective action for conveyor belts replacement has been scheduled by the establishment officials.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	Oto Urban 3/24/05

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
Oy Snellman Ab, Pietarsaari, Finland	3 – 4 - 05	62	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	
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.	X
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	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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	X
57. Monthly Review	
58. BSE	X
59. NOID	X

60. Observation of the Establishment

Finland, 3-4-05 Continuation Est.62

10/51 Several carcasses were observed contacting the platform floor where plant employees were walking. This had been identified on previous supervisory visits, but was still ongoing (9 CFR 416.13(c); 416.17).

10 Dripping condensation observed over product in boning room. Proper corrective action was performed by the establishment officials (9 CFR 416.13.c.).

13/51.SSOP records did not sufficiently document the procedures taken in response to contamination of product, or product-contact surfaces. In several instances, "preventive measures" where not documented (9 CFR 416) as part of the establishment's corrective actions taken in response to SSOP issues. Furthermore, documentation of the monitoring of operational sanitation consisted solely in employees "initialing a box" once SSOP monitoring was complete. Review of the establishment's SSOP plan indicated that employees would document all "observations" related to operational SSOP monitoring, and the initialing of a single box neither meets the expectations of their written plan, nor general FSIS policy regarding SSOP documentation ((9 CFR 416.16(a); 416.17).

20/51 The establishment lacked proper corrective actions for deviations concerning the carcass chilling CCP. The inspection service requested speedy corrective action (9 CFR 417.3b; 417.8).

41/56 Beaded condensation was observed over product in the carcass cooler and offal room (9 CFR 416.2d) EC Dir.64/433 Ch. I.(n).

45/51/56 Two conveyor belts in the boning room were in need of repair. This deficiency was scheduled for corrective action by the establishment officials (9 CFR 416.3a) EC Dir. 64/433, Ch. III.(c).

45/51/56 White containers, ready for edible product use, were being stored on the floor. No corrective action was observed during the audit (9 CFR 416.3) EC Dir. 64/433).

59 This establishment was issued a NOID by the Finnish inspection service for SSOP and HACCP deficiencies.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 3/24/05

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
Koiviston Teurastamo Oy MELLILÄ, Finland	03 – 01 - 05	85	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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 SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
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	O
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	
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

Finland, 03-01-05 Continuation Est.85

No comments.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 3/24/05

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/HK Ruokatalo Oyj VANTAA, Finland	03 – 03 - 05	6475	Finland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	
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	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
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	O
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	X
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

Finland, 03-03-05, Continuation Est. 6475

10/51 Several damaged boxes, one with the exposed product, were observed in the cold store. The compromised product was condemned according the establishment SSOP requirements (9 CFR 416.13.(c); 416.17).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Oto Urban	Oto Urban 3/24/05

Embassy of the United States of America

July 1, 2005

Sally White, Director
International Equivalence Staff
Office of International Affairs
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington D.C. 20250

Dear Ms. White:

Please find enclosed a letter from the Finnish National Food Agency with comments on the Draft Final audit report for Finland for this year.

Best regards,

Margaret E. Thursland
Agricultural Counselor
U.S. Embassy, Stockholm

Foreign Agricultural Service
American Embassy
Dag Hammarskjölds Väg 31
SE-115 89 Stockholm, Sweden

Tel:
+46-8-783 53 90

Fax:
+46-8-662 84 95

E-mail:
agstockholm@usda.gov

ELINTARVIKEVIRASTO
Livsmedelsverket • National Food Agency

June 23, 2005 1163/43/05

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

Dear Dr. White

In the Draft Final Audit Report for the annual audit of Finland's meat inspection system February 23. – March 11, 2005 there was a following comment: "In one establishment, porcine is slaughtered, the lines are washed and then bovine are slaughtered. In the same establishment, porcine and bovine are deboned at the same time in the boning room."

In the establishment (Approval number: 62), of which the comment concerned, porcine is slaughtered in the morning, after which the slaughtering line is washed, and then bovine is slaughtered in the afternoon. This separation in time and the cleaning of the slaughter line between species will certainly address the possible risk of cross-contamination. In addition the establishment has different splitting saws for both species. In the boning room both species are deboned at the same time, but in separate cutting lines, by workers dedicated to their line.

Earlier on, this has not been a problem and we have not heard that the requirements would have changed. We would appreciate if you could inform us, if the practice used in the establishment No. 62 is approvable according to the USDA/FSIS regulations or if the establishment should alter it's slaughtering or cutting practices somehow, and in that case what are the requirements.

Yours sincerely,

Osmo Mäki-Petäys
Director
Meat and Fish Hygiene Unit

Marjoriikka Keränen
Senior Officer
Meat and Fish Hygiene Unit

cc: Lorenzo Terzi, European Comission, DG SANCO E3

Elintarvikevirasto
PL 28 (Vanha talvitie 5)
00581 Helsinki
puh. (09) 393 1500
fax (09) 393 1590
info@elintarvikevirasto.fi
www.elintarvikevirasto.fi
Etunimi.Sukunimi@elintarvikevirasto.fi

Livsmedelsverket
PB 28 (Gamla vintervägen 5)
00581 Helsingfors, Finland
tel. (09) 393 1500
fax (09) 393 1590
info@elintarvikevirasto.fi
www.elintarvikevirasto.fi/svenska
Förnamn.Efternamn@elintarvikevirasto.fi

National Food Agency
PO Box 28 (Vanha talvitie 5)
00581 Helsinki, Finland
Tel. +358 9 393 1500
Fax +358 9 393 1590
info@nfa.fi
www.nfa.fi/english
Firstname.Lastname@nfa.fi