



United States
Department of
Agriculture

Food Safety
and Inspection
Service

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Dr. Osmo Mäki-Petäys
Head of the Meat Hygiene Unit
National Veterinary and Food Research Institute
Hameentie 57
FIN-00231 Helsinki
Finland

Dear Dr. Mäki-Petäys:

Enclosed is a copy of the final report of an audit of Finland's meat inspection system conducted by the Food Safety and Inspection Service from March 5, 2003, through March 24, 2003. No comments were provided by Finland to the draft final audit report.

If you have any questions or need additional information, please contact me. My telephone number is 202-720-3781, my email address is sally.stratmoen@fsis.usda.gov, and my fax number is 202-690-4040.

Sincerely,

for Sally Stratmoen, Acting Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Mikko Kinnunen, Second Secretary, Embassy of Finland
Lana Bennett, Agriculture Counselor, FAS, U.S. Embassy, Sweden
Norval Francis, Minister/Counselor for Agricultural Affairs, USEU/Brussels
Joerg Niederberger, Ag./Consumer Affairs, EU Mission to the US, Wash., DC
James Dever, Area Officer, FAS
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, Office of International Affairs, FSIS
Donald Smart, Director, Review Staff, PEER, FSIS
Amy Winton, State Department
Dave Young, FAS
Clark Danford, Acting Director, IEPS, OLA
Sally Stratmoen, Acting Director, IES OLA
Richard F. Brown, IES, OLA
Shannon McMurtrey, IES, OLA
Country File (Finland FY 2003 Audit)

FINAL

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

MARCH 5 THROUGH MARCH 24, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (National Food Agency, NFA)
<i>E. coli</i>	<i>Escherichia coli</i>
EELA	National Veterinary and Food Research Institute
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction Systems /Hazard Analysis and Critical Control Point
PVOs	Provincial Veterinary Officers
NFA	National Food Agency
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedure(s)
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Finland from March 5 through March 24, 2003.

An opening meeting was held on March 5 in Helsinki with the Central Competent Authority (CCA), the National Food Agency (NFA). In this meeting, the FSIS auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Finland's meat inspection system.

The FSIS auditor was accompanied during the entire audit by representatives from the CCA.

2. OBJECTIVE OF THE AUDIT

This was a follow-up audit, to assess the effectiveness of corrective actions taken as a result of deficiencies identified during the previous FSIS audit of Finland's inspection system in September 2002 and 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 (once for a review of centrally-located documents and once for government oversight discussions); one regional office; one private laboratory in an establishment, in which microbiological testing of United States-eligible product was performed; the government laboratory performing analytical testing for residues in United States-eligible product; three swine slaughter and pork processing establishments; and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	2	
	Provincial	1	Provincial Veterinary Office in Vaasa
Laboratories		2	
Meat Slaughter/Processing Establishments		3	
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 an audit of a selection of records in Finland's inspection headquarters and regional offices. The third part involved on-site visits to three slaughter/processing establishments and one cold storage facility. The fourth part involved visits to one government laboratory and one private laboratory. The National Veterinary and Food Research Institute was conducting analyses of field samples for

Finland's national residue control program. The microbiology laboratory in Establishment 62 was conducting analyses of samples from animals slaughtered in this establishment for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species.

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

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

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

Second, in areas not covered by these directives, the auditor would audit against 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 testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Finland under provisions of the Sanitary/Phytosanitary Agreement.

- Several equivalence determinations regarding testing procedures for generic *E. coli* and *Salmonella* species had been made. Details are discussed in Sections 11.3 and 13.2, respectively.

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 β -agonists”

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS website at www.fsis.usda.gov/fo/tsc.

The following concerns arose as a result of the FSIS audit of Finland’s inspection system, conducted in August 2001:

- ◆ *Condemned materials were not denatured in four of the six slaughter establishments in 2000 and in one of the six in 2001.*
- ◆ *In five of the six slaughter establishments, statistical control procedures had not been fully developed to evaluate E. coli testing results.*

Both of these concerns had been addressed and corrected by the September 2002 audit. An additional concern had been partly addressed:

- ◆ *During the 2000 audit, it was determined that in-plant inspection staff had not had adequate HACCP-Pathogen Reduction training.*

Additional HACCP training had been provided by the September 2002 FSIS audit, but monitoring of establishment compliance was not consistent, and some serious deficiencies had not been noted.

The following deficiencies were identified during the FSIS audits of Finland’s inspection system conducted both in August 2001 and in September 2002 (these were repeat findings):

- ◆ *In August 2001, it was found that internal reviews had not been performed monthly in three establishments.*

During the September 2002 audit, it was again determined that internal reviews had not been performed monthly in three establishments.

- ◆ *Personal hygiene problems were found in three of the seven establishments in August 2001.*

During the September 2002 audit, personal hygiene problems were found in one of the five establishments audited.

- ◆ *In one establishment, the documentation of pre-operational sanitation activities was not performed as required in the written plan, and corrective actions were not adequately described.*

This was a repeat finding in one establishment in September 2002.

- ◆ *In August 2001, alternate methodologies were being used for the culturing of field samples for generic E. coli and Salmonella species, that had not been submitted to FSIS as required for equivalence determination.*

During the September 2002 audit, alternate methodologies were still in use for both generic *E. coli* and *Salmonella* species.

- ◆ *At the time of the August 2001 audit, no species verification was being performed in any of the establishments.*

This had not been corrected by the September 2002 audit.

- ◆ *At the time of the August 2001 audit, no unknown or blank intra-laboratory check samples for organophosphates were being provided to analysts.*

By the time of the September 2002 audit, one check sample for organophosphates had been run. If this determination is run only twice per year, a check sample should be run with each one.

- ◆ *In one establishment, condensation was out of control and dripping continuously above the beef skinning area and in the beef carcass cooler. No effective corrective actions were taken on the day of the audit, and preventive measures in response to documented identification of the problem (in the cooler) had been ineffective.*

The same problem was again found in the same establishment in September 2002.

- ◆ *In one establishment, several slaughter employees were observed to fail to wash their hands after contaminating them before continuing operations.*

The same problem was again found in the same establishment in September 2002.

During the most recent audit of Finland, conducted by FSIS in September 2002, the following additional deficiencies were found:

Government Oversight

- ◆ *NFA's internal reviewers had found serious insanitary dressing in one establishment on two separate occasions and had not taken adequate regulatory action.*

The establishment failed to meet basic FSIS requirements and was delisted by NFA.

- ◆ *In one establishment, HACCP implementation deficiencies resulted in a Notice of Intent to Delist if they are not corrected within 30 days.*

These deficiencies should have been identified by NFA before the FSIS audit.

Facilities and Equipment

- ◆ *In one establishment, light intensities of 385 Lux (35 foot-candles) and 110 Lux (10 foot-candles) were measured in abdominal cavities of swine carcasses at the routine post-mortem inspection station and at the side rail, respectively. Prompt corrective actions were taken. This was in violation of both E.C. and U.S. requirements.*
- ◆ *In two establishments, several stainless combo bins, being used for exposed product, were cracked and in need of repair.*
- ◆ *In one establishment, several white plastic containers, intended for edible product, were found to be used for other purposes, without being labeled appropriately.*

SSOP and General Sanitation

- ◆ *In one establishment, pre-operational cleaning of some product-contact equipment was inadequate.*
- ◆ *In one establishment, maintenance of over-product structures had been seriously neglected in several areas.*
- ◆ *In one establishment, the "weekly" documentation of the majority of the operational sanitation activities had not been documented at all during two weeks over the course of the past two months. These activities should have been documented daily.*
- ◆ *In the cold storage facility, establishment personnel were documenting daily pre-operational sanitation activities, findings, and corrective actions, but operational sanitation activities were documented only when problems were found. These activities should have been documented daily.*

Implementation of the provisions of EC Directive 64/433

- ◆ *In each of two establishments, one swine carcass that had not been split bore the marks of inspection. This was in violation of both EC and FSIS legislation.*

In both cases, the Chief Official Veterinarians condemned the carcasses.

- ◆ *In one establishment, one of the two sterilizers at the swine evisceration station was practically empty, but was being used by the operators to “sterilize” their knives between carcasses.*
- ◆ *In 3 establishments, hand soap dispensers were missing at crucial locations.*

Slaughter and Processing Controls

- ◆ *In one establishment, seven swine carcasses railed out for trimming before final inspection had been allowed to collect on the side rail, and were in direct contact with each other.*

Contact between carcasses must be prevented until post-mortem inspection has been completed.

- ◆ *In one establishment, numerous instances of inadequate pre-boning trim were observed in both the pork and the beef cutting rooms.*

Some corrective actions were taken, but they did not include reinspection of product that had been recently processed.

- ◆ *In one establishment, the in-plant NFA personnel and the slaughter foreman were usually not notified in writing (or even orally) when contamination with ingesta or feces was found at the pre-boning trim stations, as part of the required corrective actions in the establishment’s written HACCP program. Furthermore, in the same establishment, a review of the monitoring records for the zero-tolerance CCP for visible contamination with ingesta/feces showed that the critical limit had been exceeded on six of the past 17 days, and up to three times per day on several of those days.*
- ◆ *In one establishment, the written procedure for preventive measures, to be taken when visible contamination with ingesta or feces is found after the critical control point for zero tolerance, was not followed.*

Pathogen Reduction Testing

- ◆ *Sampling for pathogen reduction testing was not conducted properly in the slaughter establishment in which the procedure was observed: the person performing the sampling did not use an aseptic technique and contacted other parts of the carcass with her gloves and with the gauze swab.*
- ◆ *NFA had informed FSIS that NFA personnel were taking the samples for testing for generic E. coli. In all establishments, however, establishment personnel were taking the samples. FSIS had not been notified of the change in sampling procedure.*

- ◆ *NFA had informed FSIS that establishment personnel were taking the samples for testing for Salmonella species. In one establishment, however, NFA personnel were taking the samples.*

Residue Laboratory

- ◆ *There were no written corrective action programs to be followed in the event that an analyst's performance did not meet expectations.*

6. MAIN FINDINGS

6.1 Legislation

The relevant EC Directives, determined equivalent under the VEA, had been transposed into Finland's legislation.

6.2 Government Oversight

The National Food Agency (NFA) is responsible for directing, planning, and developing food control in Finland and for conducting control. Activities of the NFA and the Plant Production Inspection Centre cover the control of all foodstuffs from field to table. The NFA guides the municipal food control authorities, provincial state offices, and the National Board of Customs, which perform the practical control. The NFA is a subordinate agency of the Ministry of Agriculture and Forestry.

6.2.1 CCA Control Systems

The 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 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 officials) belong to this Unit. The NFA cooperates closely with the National Veterinary and Food Research Institute (EELA), the National Public Health 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 two in the Province of Southern Finland. The audit included a visit to the Provincial Veterinary Office in the Province of Western Finland.

Guidelines have been developed by a crisis working group in NFA to be implemented in case any terrorism activities are suspected and are ready for distribution to field employees in the event that it is needed.

6.2.2 Ultimate Control And Supervision

The tasks of the NFA include meat inspection and control in slaughterhouses and connected establishments, approval of the slaughterhouses and connected establishments, national residue and testing programs for *Salmonella* 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. 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 NFA Senior Veterinary Officers in Helsinki. More information on the internal review system is provided in Section 13.4 of this report.

The PVOs discuss their routine evaluations of the performances of the in-plant inspection personnel with the latter during their internal reviews—and, if any issues of concern arise, discuss these with their supervisors after the audits are completed. The PVOs' supervisory evaluations may, but are not required to be documented in writing; they usually make personal notes in their own files.

Supervision of inspectors at the local level in the certified establishments has improved considerably since the previous FSIS audit. There is documented evidence of inspection system controls at all levels. 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 is being implemented.

Since the previous FSIS audit in September 2002, U.S.-export eligibility was temporarily suspended in two establishments:

- In one of these, U.S. eligibility was suspended by the Veterinarian-In-Charge in the last week of February 2003, when swine slaughter was resumed after a period of construction and problems with excessive hair contamination were identified. The suspension was still in effect on the day of the audit of this establishment; no problems involving excessive hair were observed during the audit.
- In the other establishment, a Notice of Intent to Delist was issued by NFA on February 28, 2003, as a result of failure to monitor CCPs as required and inadequate implementation of the requirement for pre-shipment reviews. The establishment's

U.S.-export eligibility was suspended until the deficiencies were corrected to NFA's satisfaction, one week later, and the affected product was excluded from the U.S. export chain.

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) NFA, (2) EELA, and (3) the Ministry of Agriculture and Forestry.

It is noteworthy that, in all four establishments currently listed as eligible to export to the U.S., all deficiencies identified during the previous FSIS audit had been addressed and corrected. There were no repeat deficiencies.

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 "full-throughput" establishments. Non-veterinary "auxiliaries" have courses involving 200 hours of practical training on a slaughter line and 400 hours of theoretical classwork, after which they must also pass specific examinations before being qualified to work in export meat establishments.

In-plant inspection personnel, their supervisors (the Provincial Veterinarians), and headquarters officials have participated in additional HACCP training sessions since the last FSIS audit, and no deficiencies in their monitoring of establishment compliance with HACCP requirements were noted during this audit.

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 (but not establishment-paid individuals) may be hired as temporary or part-time government employees in establishments certified for U.S.-export.

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

6.2.4 Authority and Responsibility to Enforce the Laws

NFA has the authority and the responsibility to enforce U.S. and E.C. requirements.

6.2.5 Adequacy of Administrative and Technical Support

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. NFA is responsible for hiring veterinarians and other inspection personnel, and determines the allocation of personnel to the establishments.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service and in all the local offices in the establishments visited. 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, including courses in HACCP and SSOP,
- Animal disease status,
- Supervisory visits to U.S. certified establishments,
- Labeling records,
- New laws and implementation documents such as regulations, notices, directives and guidelines regarding the separation of materials at risk for transmissible spongiform encephalopathies (TSE), hygiene requirements for storage establishments, supervision of establishments, and enforcement procedures related to handling of foodstuffs,
- Official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed,
- Sampling and laboratory analyses for residues,
- Sanitation, slaughter and processing inspection procedures and standards,
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials,
- The new species verification policy and program implemented on 12/12/02 since the previous FSIS audit in September 2002, and
- Export product inspection and control including export certificates.
- Enforcement actions were also discussed. See Section 6.2.2.

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

6.3.1. Audit of Regional and Local Inspection Sites

The provincial inspection office in Vaasa was audited on March 11, 2003, and the Provincial Veterinarian for the province of Western Finland was interviewed to gain further insight into the oversight of establishment-level inspection controls. No concerns arose as a result of this interview.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four establishments—three slaughter/processing establishments and one cold-storage facility. No establishments were delisted during this audit as a result of failure to meet FSIS requirements.

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 calibration and operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt and handling, timely analysis, analytical methodologies, equipment calibration and operation, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test samples for U.S.-eligible samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

In Finland, the microbiological testing for generic *Escherichia coli* (*E. coli*) and *Salmonella* species is conducted in private laboratories in the establishments in which the livestock is slaughtered.

The following laboratories were audited:

- The private microbiology laboratory in Establishment 62. The findings in this laboratory are discussed in Sections 11.3 (Testing for generic *E. coli*) and 13.2 (Testing for *Salmonella* species) of this report.
- The government-owned and -operated National Veterinary and Food Research Institute in Helsinki, in which analysis of field samples for the national residue testing program is conducted. The findings in this laboratory are discussed in Section 12 (RESIDUE CONTROLS) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviews is 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 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. The NFA Senior Veterinary Officers ordered corrective actions and preventive measures.
- ◆ In one establishment, general housekeeping in the chemical storage area had been neglected. This was identified by the NFA officials and corrective actions were ordered and begun immediately, and were completed by the end of the day of this audit.

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

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. In all four establishments, the SSOP were found to meet the basic FSIS regulatory requirements.

9.2 EC Directive 64/433

In all four establishments, the provisions of EC Directive 64/433 regarding general sanitation were effectively implemented.

10. ANIMAL DISEASE CONTROLS

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

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit. Beef from Finland is under APHIS restriction due to a confirmed case of Bovine Spongiform Encephalopathy (BSE).

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem 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 noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented HACCP programs. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the three establishments in which they were required. In all three establishments, the PR/HACCP requirements had been adequately implemented.

11.3 Testing for Generic *E. coli*

Finland has adopted the FSIS regulatory requirements for generic *E. coli* testing, with the exception of the following measure that has been determined to be equivalent by FSIS:

- The government officials take the samples.
- An alternative sampling rate (1 per 5,000) for swine is used; this is acceptable since this frequency is part of a validated HACCP plan.

Testing for generic *E. coli* in Finland is performed in private laboratories in the slaughter establishments.

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

In all three slaughter establishments, statistical process control methods had been developed and implemented, as required, to evaluate the results of the testing programs for generic *E. coli*.

Sampling procedures for generic *E. coli* were properly conducted in all of the three slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

In the three establishments producing ready-to-eat products (not for U.S. export), testing programs for the control of *Listeria monocytogenes* had been developed and implemented.

11.5 EC Directive 64/433

In two of the three slaughter-and-processing establishments, the provisions of EC Directive 64/433 regarding slaughter and processing controls were effectively implemented. The following deficiency was noted:

- ◆ In one establishment, cross-contamination was observed between a carcass that was railed out for trimming of a hock swelling and another carcass that had fallen on the floor. The NFA officials ordered them to be separated immediately and ordered that the affected areas on the former carcass be trimmed and condemned.

12. RESIDUE CONTROLS

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

The National Veterinary and Food Research Institute (EELA) in Helsinki was audited. No deficiencies were noted.

Finland's National Residue Control Program for 2003 was being followed and was on schedule.

12.1 FSIS Requirements

In the EELA Laboratory, the FSIS requirements were effectively implemented.

12.2 EC Directive 96/22

In the EELA Laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.3 EC Directive 96/23

In the EELA Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

Since the previous FSIS audit, there were no incidents of criminal prosecution, consumer complaints, recalls, or seizure and control of non-compliant product or withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States. The eligibility of two establishments to produce product for U.S. export was temporarily suspended in two establishments (see Section 6.2.2 for details).

The Auditor advised the NFA officials of the FSIS website in general, and advised them of the availability of the Quarterly Enforcement Report in particular. The Finnish officials responded that, in the Finnish system, there was no equivalent material that was made routinely available to the general public, but that enforcement actions, as well as all official reports made from reviews of establishments, except for proprietary information, are available to the public upon request.

13.1 Daily Inspection in Establishments

Inspection was being conducted and documented daily in all slaughter and processing establishments.

13.2 Testing for *Salmonella* Species

Finland had adopted the FSIS regulatory requirements for testing for *Salmonella* species with the exception of the following measures that have been determined to be equivalent by FSIS:

- A gauze swab-pad sampling tool is used.
- Establishment employees take the samples, under the supervision of NFA.
- Private laboratories analyze samples.
- The sampling program is continuous and ongoing.
- Samples are taken at the end of slaughter/production.
- Samples are composited at the laboratory.
- Laboratories use the ISO 6579 method to analyze for *Salmonella* species.
- Samples are collected from two large sites on cattle carcasses.

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

13.3 Species Verification

At the time of this audit, Finland was required to test product for species verification.

NFA officials had developed and (on December 12, 2002) implemented a new species verification program. A minimum of five samples are taken by either in-plant NFA officials or establishment personnel under the direct supervision of the Veterinarians-In-Charge, in each of the three processing establishments and analyzed in the EELA laboratory, using immuno-chemical analytical procedures.

13.4 Monthly Reviews

As stated earlier in this report, Finland is divided into 5 provinces. Each has two or more Provincial Veterinary Officers (PVOs). There are a total of 21 PVOs at the time of this audit; all are full-time employees of the Ministry of Internal Affairs. These are the officials who routinely conduct the supervisory visits to establishments certified by Finland as eligible to export meat products to the United States. They are also responsible for animal welfare and disease control. Their reports of reviews of the U.S.-eligible establishments are sent directly to the Director of the Meat and Fish Hygiene Unit. In the event of illness or other circumstances that may prevent these officials from performing the monthly visits, Senior Veterinary Officers from NFA headquarters will fill in.

Meat inspection is included in the veterinary curriculum (a strong emphasis is placed on meat hygiene during the fourth year of the six-year program).

All information, guidelines, notices, directives, etc. provided to in-plant inspection staff are also sent to the PVOs.

The monthly internal review program is applied only to export plants. The visits are usually announced about a week in advance to the Veterinarian-In-Charge, and enough (several days') notice is usually given to the establishment that a management representative will be present for the review. Unannounced visits are employed in the event of special circumstances or suspected problems. Senior Veterinary Officers from NFA headquarters also conduct independent audits of the establishments and, on these occasions, the PVOs are notified in advance, and are welcome to attend these audits as their schedules permit.

The internal reviews are usually conducted by a single reviewer, with a target frequency of at least once during each month when an establishment produces any product that is eligible for export to the U.S. Records of reviewed plants are kept centrally (at NFA headquarters), in the offices of the PVOs, and in the establishments, and are maintained on file for at least five years.

The internal reviewers have an advisory function. They report their findings to the Director of the Meat and Fish Hygiene Unit, who then decides what actions are to be taken. Routine reports are sent by mail and can take from one to four weeks to be

reported to the Director of the Meat and Fish Hygiene Unit. In the event of noncompliance, the PVOs convey the results to their supervisors by telephone. In the event that an establishment is determined to be unacceptable as a result of failure to meet U.S. requirements during a routine internal audit, all other U.S.-eligible establishments and cold stores are immediately informed, and International Policy Division in Washington, D.C. is also immediately notified, through the Agricultural Counselor in Stockholm. If the establishment management wishes to regain eligibility for access to the U.S. market, the management contacts NFA and requests another internal review. If noncompliances are identified that are not serious enough to warrant delistment, there are provisions for U.S. eligibility to be temporarily suspended, pending corrective actions.

FSIS requires documented supervisory visits by a representative of the foreign inspection system, not less frequent than one such visit per month to each establishment certified, during periods when the establishment is engaged in producing products for exportation to the United States.

During this audit it was found that, since the last FSIS audit of Finland's meat inspection system in September 2002, monthly supervisory reviews had been performed and documented as required in all establishments.

13.5 Inspection System Controls

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

No livestock or meat was imported from third countries for product eligible for export to the United States.

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 with the CCA by teleconference on March 24, 2003. During this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

15. ATTACHMENTS

- A. Individual Foreign Laboratory Review Forms
- B. Individual Foreign Establishment Audit Checklists
- C. Country Response (no written response received)

rev Dr. Gary D. Bolstad
International Audit Staff Officer

Oto Urban

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY National Food Agency	CITY & COUNTRY Helsinki, Finland	ADDRESS OF LABORATORY P.O. Box 45 (Hämeentie 57)
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Dr. Kemmo Peltonen, Director; Ms. Seija Berg; Dr. Eija Laikko	

Residue Code/Name			chc	pob	abc	cap	tet	op	te	des	sul	ivm			
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01	A	A	A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A	A	A		
	Timely Analyses	03	A	A	A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O	O	O		
Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A			
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A			
	Correct Tissue(s)	08	A	A	A	A	A	A	A	C	C	C			
	Equipment Operation	09	A	A	A	A	A	A	A	A	A	A			
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A	A			
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A	A			
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A	A			
	Percent Recovery	13	A	A	A	A	A	A	A	A	A	A			
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A			
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A	A			
	Corrective Actions	16	A	A	A	A	A	A	A	A	A	A			
	International Check Samples	17	A	A	O	A	O	A	A	O	A	O			
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A	A			
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER *Dr. Gary D. Bolstad*

DATE 3/18/03

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE March 18, 2003	NAME OF FOREIGN LABORATORY National Veterinary and Food Institute (EELA)
FOREIGN GOV'T AGENCY National Food Agency		CITY & COUNTRY Helsinki, Finland	ADDRESS OF LABORATORY P.O. Box 45 (Hämeentie 57)
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Kemmo Peltonen, Director; Ms. Seija Berg; Dr. Eija Laikko	

A-16

RESIDUE	ITEM	COMMENTS
(des,sul)	(08)	<p>Abbreviations: chc = chlorinated hydrocarbons, abc = antibiotics, cap = chloramphenicol, tet = tetracyclines, des = diethylstilbestrol, sul = sulfonamides, and ivm = ivermectin.</p> <p>(The following tissue matrices were used: for DES - urine and feces, for sulfonamides - muscle, and for ivermectin - liver.)</p>

A-2a

Mar 10, 2003

Est. 62, Oy Snellman Ab

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY

CITY & COUNTRY

ADDRESS OF LABORATORY

Oversight by the National Food Agency

Pietarsaari, Finland

Pietarsaari, Finland

NAME OF REVIEWER

Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL

Drs. Anna-Majja Grönlund, Marjoriikka Keränen, Eeva Japisson, and Riitta Mangs

Residue Code/Name		Ecol	Sal																
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																
	Sample Handling	01		A	A														
	Sampling Frequency	02		A	A														
	Timely Analyses	03		A	A														
	Compositing Procedure	04		O	O														
	Interpret Comp Data	05		O	O														
Data Reporting	06	A	A																
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A															
	Correct Tissue(s)	08	A	A															
	Equipment Operation	09	A	A															
	Instrument Printouts	10	O	O															
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O	O															
	Recovery Frequency	12	A	A															
	Percent Recovery	13	O	O															
	Check Sample Frequency	14	A	A															
	All analyst w/Check Samples	15	A	A															
	Corrective Actions	16	A	A															
	International Check Samples	17	A	A															
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O	O															
OTHER REVIEW		19																	
		20																	

SIGNATURE OF REVIEWER

Dr. Gary D. Bolstad

DATE

3/10/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

Mar 10, 2003

NAME OF FOREIGN LABORATORY

Est. 62, Oy Snellman Ab

A-2b

FOREIGN GOV'T AGENCY Oversight by the National Food Agency	CITY & COUNTRY Pietarsaari, Finland	ADDRESS OF LABORATORY Pietarsaari, Finland
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. Anna-Majja Grönlund, Marjoriikka Keränen, Eeva Japisson, and Riitta Mangs	

RESIDUE	ITEM	COMMENTS
(Both)	(01)	(Sampling is performed as agreed upon with FSIS: establishment personnel (laboratory technicians) take the swab samples for <i>Salmonella</i> , and NFA officials take the swab samples for <i>E. coli</i> . Also, the sampling rate is as agreed upon with FSIS: one per 500 swine and one per 1,500 cattle.)
(Both)	(15)	(Intralaboratory check samples are done monthly for both <i>Salmonella</i> and <i>E. coli</i> .)

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Ruokatalo Oy Teollisuuskatu 17 Forssa	2. AUDIT DATE March 17, 2003	3. ESTABLISHMENT NO. 18	4. NAME OF COUNTRY Finland
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 18. HK Ruokatalo Oy, Forssa, Finland, March 17, 2003

39 Maintenance and cleaning of over-product equipment and 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. Also, in several production areas, writing implements and papers for documentation, as well as computer terminals and printers, were not maintained and stored under sanitary conditions. The NFA Senior Veterinary Officers ordered an improved maintenance and cleaning schedule, with increased attention to these areas during pre-operational sanitation inspection by establishment personnel and increased monitoring by in-plant NFA officials.

46/56 Cross-contamination was observed between a carcass that was railed out for trimming of a hock swelling and another carcass that had fallen on the floor. The NFA officials ordered them to be separated immediately and ordered that the affected areas on the former carcass be trimmed and condemned.

Accompanying NFA officials: Drs. Anna-Maija Grönlund and Marjoriikka Keränen, Senior Veterinary Officers, Food Control; Dr. Inna Ilivitzky, Provincial Veterinarian; and Dr. Juhani Koivumäki, Chief Official Veterinarian.

61. NAME OF AUDITOR

Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

 3/17/03

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Atria Oyj Nurmo	2. AUDIT DATE March 12, 2003	3. ESTABLISHMENT NO. 22	4. NAME OF COUNTRY Finland
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 22, Atria Oyj, Nurmo, Finland, March 12, 2003

- 39 Maintenance and cleaning of over-product equipment and 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. The NFA Senior Veterinary Officers ordered an improved maintenance and cleaning schedule, with increased attention to these areas during pre-operational sanitation inspection by establishment personnel and increased monitoring by in-plant NFA officials, and stated that they would conduct a follow-up review of this establishment within 30 days to ensure the effectiveness of the improvements.

NOTE: All deficiencies identified during the previous FSIS audit on 9/9/2002 had been adequately addressed and corrected.

Accompanying NFA Officials: Drs. Anna-Maija Grönlund and Marjoriikka Keränen,, Senior Officers, Food Control; Dr. Eeva Japissou, Provincial Veterinarian; Dr. Heikki Takala, Veterinarian-In-Charge.

61. NAME OF AUDITOR

Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

 3/12/03

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Oy Snellman Ab Pietarsaari	2. AUDIT DATE March 10, 2003	3. ESTABLISHMENT NO. 62	4. NAME OF COUNTRY Finland
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 62, March 12, 2003, Pietarsaari, Finland, March 10, 2003

39 General housekeeping in the chemical storage area had been neglected. This was identified by the NFA officials and corrective actions were ordered and begun immediately, and were completed by the end of the day of this audit.

NOTE: All deficiencies noted during the previous FSIS audit on September 11, 2002 have been completely addressed and corrected.

Operations: Swine and beef slaughter; pork and beef cutting, boning, curing, and (not for U.S. export) ground beef and processed meats in consumer packages. Exports to the U.S.: pork ribs. One shift for slaughter and cutting; two shifts for slicing, packaging, and shipping of processed meat products.

Accompanying MFA personnel: Dr. Anna-Maija Grönlund, Dr. Marjoriikka Keränen, Dr. Eeva Japissou, Dr. Riitta Mangs (Veterinarian-In-Charge)

NOTE: This establishment's U.S. eligibility was temporarily suspended by the Veterinarian-In-Charge in the last week of February 2003, when swine slaughter was resumed after a period of construction and problems with excessive hair contamination were identified. The suspension was still in effect on the day of the audit of this establishment. No problems involving excessive hair were observed on the day of the audit.

61. NAME OF AUDITOR

Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

 3/10/03

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Roukatalo Oyj/Pakastamo Oy 01511 Vantaa	2. AUDIT DATE March 14, 2003	3. ESTABLISHMENT NO. 6475	4. NAME OF COUNTRY Finland
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling		Audit Results
7. Written SSOP			33. Scheduled Sample		O
8. Records documenting implementation.			34. Species Testing		O
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue		O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements		
10. Implementation of SSOP's, including monitoring of implementation.			36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import		
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan .		O	41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		O	42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.		O	43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.		O	44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
18. Monitoring of HACCP plan.		O	46. Sanitary Operations		
19. Verification and validation of HACCP plan.		O	47. Employee Hygiene		
20. Corrective action written in HACCP plan.		O	48. Condemned Product Control		O
21. Reassessed adequacy of the HACCP plan.		O	Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		O	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily inspection Coverage		
23. Labeling - Product Standards		O	51. Enforcement		
24. Labeling - Net Weights		O	52. Humane Handling		O
25. General Labeling		O	53. Animal Identification		O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		O	54. Ante Mortem Inspection		O
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		O
27. Written Procedures		O	Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis		O	56. European Community Directives		
29. Records		O	57. Monthly Review		
Salmonella Performance Standards - Basic Requirements			58.		
30. Corrective Actions		O	59.		
31. Reassessment		O			
32. Written Assurance		O			

60. Observation of the Establishment

Est. 6475, HK Roukatalo Oyj/Pakastamo Oy, Vantaa, Finland, March 14, 2003

(34) Samples for species verification are being taken in the establishments of origin.

(50) Daily inspection coverage is not required in cold-storage facilities. The Veterinarian-In-Charge visits this establishment several times per week, and her visits are well documented.

Note: This is a cold storage facility; there is no exposed product.

All deficiencies identified during the previous FSIS audit on September 6, 2002, had been addressed and corrected.

Accompanying NFA personnel: Drs. Marjoriikka Keränen and Anne Fagerlund, Senior Veterinary Officers; Dr. Kirsi Sario, Provincial Veterinarian; Dr. Irma Etelämäki, Official Veterinarian (in charge)

61. NAME OF AUDITOR

Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

 3/14/03

Country Response Not Received