



United States
Department of
Agriculture

Food Safety
and Inspection
Service

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3/28/03

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:

The Food Safety and Inspection Service conducted an on-site audit of Finland's meat inspection system from September 3 - 27, 2002. Enclosed is a copy of the final audit report dated February 18, 2003. Comments by Finland on the draft final audit report have been included as an attachment to the enclosed final audit report.

As stated in our November 25, 2002 letter, FSIS is intent on ensuring that countries take appropriate corrective actions in response to deficiencies found during previous audits. We would also like to emphasize that several problems have been observed during the September/October 2000, August 2001, and September 2002 audits that had not been adequately addressed by the government of Finland. The 2002 audit resulted in one establishment being decertified and one being given a 30-day notice as a direct result of these unaddressed deficiencies.

In addition, FSIS found alternative sanitary measures in use that had not been determined equivalent through FSIS' equivalence process. FSIS expects the central competent authority of Finland to advise FSIS of potential alternative sanitary measures and obtain a positive equivalence determination before they are implemented. One such sanitary measure was the analysis of individual samples for *Salmonella* species rather than compositing the samples at the laboratory. Another such sanitary measure was allowing government and/or establishment personnel to collect *Salmonella* species and generic *E. coli* samples

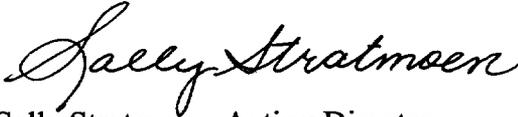
FSIS appreciates your subsequent submission on allowing government and/or establishment personnel to collect *Salmonella* species and generic *E. coli* samples. However, as a result of various e-mail inquiries from both parties, we were advised by your office that you were considering how you will proceed. Consequently, FSIS would like to know if you intend on pursuing this equivalence request.

FSIS has not received an equivalence request regarding the analysis of individual samples for *Salmonella* species. FSIS would appreciate a response in this regard.

The problems noted above have a distinct impact on FSIS' evaluation of Finland's meat inspection system. The audit observations noted in the audit report and in our letter of November 25, 2002 reflect weaknesses in inspection system controls, government oversight, and the enforcement of FSIS and EC Directives. Consequently, I would like to invite you to participate in one or more teleconferences with FSIS to resolve these issues and seek a better understanding of the equivalence of our inspection systems.

Regarding Finland's comments to the draft final audit report, FSIS has carefully reviewed your comments of February 3, 2003 and have made the appropriate changes to the 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.stratmoen@fsis.usda.gov.

Sincerely,



Sally Stratmoen, Acting Director
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
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Richard F. Brown, ES, OIA
Country File (FY 2002 Audit)

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

SEPTEMBER 3 THROUGH 27, 2002

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
IPS	International Policy Staff
NFA	National Food Agency
SSOP's	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Finland from September 3 through September 27, 2002.

An opening meeting was held on September 3 in Helsinki with the Central Competent Authority (CCA), the National Food Agency (NFA). At 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 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, one laboratory performing microbiological testing on United States-eligible product, one laboratory performing analytical testing for residues in United States-eligible product, four swine slaughter and pork processing establishments, and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	3	
	Local	5	Establishment level
Laboratories		2	
Meat Slaughter/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 an audit of a selection of records in the Finland's inspection headquarters and regional offices. The third part involved on-site visits to five establishments: four slaughter/processing establishments and one cold storage facility. The fourth part involved visits to one government laboratory and one private laboratory. The microbiology laboratory in Establishment 22 was conducting analyses of samples from animals slaughtered in this establishment for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species. The National Veterinary and Food Research Institute was conducting analyses of field samples for FINLAND'S national residue control program.

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'S, 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/ofotsc.

The following concerns arose as a result of the FSIS audit of Finland’s inspection system, conducted in September-October 2000:

- ◆ Dropped meat reconditioning procedures were inadequate.
- ◆ No field samples were being analyzed for arsenic or mercury, although Finland’s national residue testing plan for 2000 required this testing.

Both of these concerns had been addressed and corrected by the August 2001 audit.

The following deficiencies were identified during the FSIS audits of Finland’s inspection system conducted both in September-October 2000 and in August 2001 (these were repeat findings):

- ◆ In-plant inspection staff had not had adequate HACCP-Pathogen Reduction training.
- ◆ Condemned materials were not denatured in four of the six slaughter establishments in 2000 and in one of the six in 2001.
- ◆ In 2000, in five of the six slaughter establishments, statistical control procedures had not been developed to evaluate *E. coli* testing results. This had not been corrected in 2001; however, by the time the new audit of Finland was completed, the development of the necessary procedures was underway.

During the most recent audit of Finland, conducted by FSIS in August 2001, the following additional deficiencies were found:

- ◆ Problems were documented involving personal hygiene practices, sanitary dressing procedures, sterilization of equipment, control of condensation, lighting at post-mortem inspection stations, documentation of operational sanitation activities, and maintenance of over-product equipment.
- ◆ No unknown or blank intra-laboratory check samples for organophosphates were being provided to analysts.
- ◆ No species verification was being performed in any of the establishments.

- ◆ Finland had informed FSIS that European ISO methodologies were being used for the culturing of field samples for generic *E. coli* and *Salmonella* species. This policy had been changed, and different methods were now in use; these had not been submitted to FSIS as required for equivalence determination.
- ◆ Internal reviews (required monthly when U.S.-eligible production is conducted) had not been performed monthly in three establishments.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that 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 to 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) 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.

A guideline has been developed by a crisis-working group in NFA to be implemented in case any terrorism activities are suspected and is 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 *Salmonella* control programs on meat, and control of meat exports outside the European Union. The in-plant inspection personnel are supervised by NFA's

Senior Veterinary Officers. The Provincial Veterinary Officers, who perform the monthly internal reviews of establishments certified as eligible to produce products for U.S. export, also evaluate and report on the performance of the in-plant inspection personnel and export procedures. More information on the internal review system is provided in Section 13.4 of this report.

Supervision of inspectors at the local level in the certified establishments and evaluation of their performance have improved; however, serious inadequacies in plant-level oversight persist. 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 draft guideline, nearing completion, contains written instructions for evaluating PR/HACCP programs.

The European Union'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.

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 have received additional HACCP training since the last FSIS audit, but their monitoring of establishment compliance is not consistent, and some serious deficiencies had not been noted by these on-site inspection officials.

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. requirements; however, NFA reviewers had identified serious deficiencies, in advance of the FSIS audit, in the establishment that was delisted, and had not taken the appropriate enforcement action. More details are provided in Section 7 of this report.

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 review 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'S.
- 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.
- A draft of the species verification policy and program to be implemented
- Export product inspection and control including export certificates.
- Enforcement actions were discussed. There were no incidents of criminal prosecution, consumer complaints, recalls, 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 during the past year.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of five establishments—four slaughter/processing establishments and one cold-storage facility. One establishment received a 30-day letter from Finland because of deficiencies regarding the implementation of HACCP systems

and SSOP'S (this establishment may retain its certification for export to the United States provided that all deficiencies noted during the audit are corrected within 30 days of the date the establishment was audited). One establishment was delisted by Finland because of extensive product contamination and failure to implement the requirements of HACCP systems and SSOP'S.

It is noteworthy that recent reviews of the establishment that was delisted as a result of findings during this FSIS audit were conducted by teams of NFA Senior Veterinary Officers on two separate occasions, one on August 15, 2001 and the other on September 4-5, 2002. During both of these reviews the reviewers noted serious deficiencies, particularly regarding failure to demonstrate sanitary dressing procedures. As a result, delisting of this establishment for eligibility to produce product for U.S. export was discussed with the Director of the Meat and Fish Hygiene Unit. The NFA officials explained that, due to a misunderstanding that they were expected *not* to delist an establishment immediately prior to an FSIS audit, they elected to allow the routine audit of this establishment by the FSIS auditor to proceed as scheduled. The FSIS auditor explained the policy, informing the NFA officials that FSIS *fully expects* the CCA to delist any establishment that it determines has failed to meet basic FSIS requirements, *whenever* this determination is made.

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, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

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

The following laboratories were audited:

The private microbiology laboratory in one establishment conducts analyses of samples from animals slaughtered in this establishment for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species. The findings in this laboratory are discussed in Section 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 conducts analysis of field samples for the national residue testing program. The findings in this laboratory will be 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 Finland'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 addition, and except as noted below, 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'S

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP'S were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP'S in the five establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- ◆ 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. In the same establishment, the "weekly" documentation of the majority of operational sanitation activities had not been documented at all during two weeks over the course of the past two months.
- ◆ Establishment personnel in the cold storage facility were documenting daily pre-operational sanitation activities, findings, and corrective actions, but operational sanitation activities were documented only when problems were found. The management officials gave assurances that they understood the requirement and would implement daily documentation of operational sanitation activities; the attending NFA officials gave assurances that they would monitor compliance.

9.2 EC Directive 64/433

In three establishments, the provisions of EC Directive 64/433 regarding general sanitation were effectively implemented. In the two establishments with deficiencies, 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 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 a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the four establishments in which they were required. Two establishments had adequately implemented the PR/HACCP requirements; two had not, as follows:

- ◆ 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. On the day of the audit, the pre-boning trimmer had documented four instances of visible contamination with ingesta on carcasses entering the cutting room; the contamination had been trimmed, but no feedback had been provided as required in the written procedures. A document review indicated that, over the course of the past month, contamination with ingesta had been documented on twelve days, and the required written notification had not been provided. One beef quarter that had passed the pre-boning trim station in the cutting room was found with a small area of visible contamination with ingesta on the day of the audit; it was trimmed, and all other quarters in the cutting were ordered by the NFA officials to be reinspected (no further visible contamination with ingesta was found).

- ◆ In one establishment, the in-plant NFA personnel and the slaughter foreman were usually *not* notified in writing (or even orally) when fecal contamination 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 seventeen days, and up to three times per day on several of those days. No effective preventive measures had been taken to correct the problem.

11.3 Testing for Generic *E. coli*

According to information supplied to FSIS by Finland, Finland had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent measure:

- The government takes the samples.

Testing for generic *E. coli* is performed in private laboratories in the slaughter establishments. The sampling procedures employed were not uniform. According to information provided to FSIS in advance of this audit, NFA employees perform the sampling of the carcasses. The following deficiencies were identified:

- ◆ Establishment personnel were taking the samples in three establishments. This had been submitted to FSIS for an equivalence determination.
- ◆ The NMKL-147 method was being used for the analysis of the samples. This method was a slight modification of the AOAC Official Method 991.14 employed by FSIS. It had been submitted to FSIS for an equivalence determination.

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

In all four 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 three of the four slaughter establishments. The following deficiency was identified:

- ◆ In one establishment, the laboratory technician's technique for handling of gloves and collection tools was not aseptic, and she handled various other areas of the carcass with her "sterile" gloves between sampling sites.

11.4 Other FSIS Requirements

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

11.5 EC Directive 64/433

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

- ◆ In one establishment, several slaughter employees were observed to fail to wash their hands after contaminating them before continuing operations. This was a repeat finding. NFA officials ordered corrective actions.
- ◆ In each of two establishments, one swine carcass that had not been split as required, by both EC and FSIS legislation, prior to post-mortem inspection, bore the marks of inspection. Details are discussed in Section 13.5 of this report.

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.

12.1 EC Directive 96/22

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

12.2 EC Directive 96/23

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

12.3 Other FSIS Requirements

The following deficiencies were noted:

- ◆ Supervising chemists in charge of the various departments were responsible for determining the causes of unexpected results, but there were no actual written corrective action programs *per se* to be followed in the event that an analyst's performance did not meet expectations. The laboratory management personnel agreed to incorporate such a written corrective action program in their quality assurance procedures promptly.
- ◆ Only one intra-laboratory check sample was being run per year for organophosphates. None were done in 2001. Positive, spiked internal standards were being run with each sample; two sample sets were being run per year. (FSIS expects monthly check samples to be run, even if field samples are not analyzed monthly.) The acting laboratory director said this would be initiated immediately.

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.

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

According to information provided to FSIS by NFA prior to this audit, Finland had adopted the FSIS regulatory requirements for testing for *Salmonella* species with the exception of the following equivalent measure(s):

- 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.

Four of the five 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.

The following findings were at variance with the information provided to FSIS:

- ◆ In one establishment, NFA officials were taking the samples. This had been submitted to FSIS for an equivalence determination.
- ◆ Samples were not composited at the laboratory, but were analyzed individually.
- ◆ Two different methods were being used to analyze samples for *Salmonella* species. Some laboratories were using a method approved by FSIS (ISO 6579), while other laboratories were using Nordic Committee on Food Analysis (*Nordisk Metodikkommittee for Lizsmedel*, MNKL) method #71; the latter method had been

submitted to FSIS for an equivalency determination, but the results of the determination had not been finalized

13.3 Species Verification

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

No species verification was being performed in any of the establishments certified as eligible for export to the United States. This was a repeat finding. NFA has applied to FSIS for an exemption. NFA officials developed and implemented a species verification program before the country exit meeting on September 27 and provided the details of the program to FSIS.

13.4 Monthly Reviews

Finland is divided into 5 provinces. Each has Provincial Veterinary Officers (there were a total of 21 at the time of this audit); they are all 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 were 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 6-year program).

All information, guidelines, etc. provided to in-plant inspection staff are also sent to the Provincial Veterinary Officers.

The monthly internal review program is applied only to export plants. The visits are usually announced in advance to the Veterinarian-In-Charge, and enough notice is usually given to the establishment that a management representative would be present for the review. Unannounced visits are employed in the event of a suspected problem. 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) 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 were to be taken. Routine reports are sent by mail and can take from one week to two months to be reported to the Director of the Meat and Fish Hygiene Unit the Director of the Meat and Fish Hygiene Unit. In the event of noncompliance, results are conveyed by telephone.

In the event that an establishment is determined to fail 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.

Title 9 of the U.S. Code of Federal Regulations 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 August 2001, monthly supervisory reviews had been performed and documented in two establishments, but had not been performed and documented during one month in one establishment, during two months in one establishment, and during three months in one establishment. In the establishment in which two monthly reviews had been missed, reports of monthly reviews for two additional months had not been written although, according to the attending NFA officials, the reviews had been performed. The Provincial Veterinary Officer who had performed these two visits was no longer an internal reviewer at the time of this audit.

It was noted that, in the province with the two establishments in which one and three internal reviews were missing, an additional internal reviewer has been added to the staff, as of September 2, 2002.

13.5 Inspection System Controls

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

- ◆ In one establishment, an unsplit sow carcass observed in a cooler, on the rail reserved for thermal processing (all carcasses from sows are sent to thermal processing); the mandibular lymph nodes had not been incised and inspected. Due to a misunderstanding at the side rail, one post-mortem inspector had thought that another inspector had conducted post-mortem inspection on the carcass and had marked it with the official mark of inspection. Both European Community and FSIS regulations require splitting of the carcass before post-mortem inspection and incision and observation of the mandibular lymph nodes as part of the post-mortem inspection procedure. The Veterinarian-In-Charge identified the oversight, condemned the carcass immediately, and gave assurances that he would discuss the matter with the inspection staff to avoid any similar occurrence in the future.
- ◆ In a different establishment, a swine carcass that had not been split, yet bore the marks of inspection, was found in a cooler (the mandibular lymph nodes had been

incised). The inspection personnel were unable to offer an explanation. The carcass was condemned by the Chief Official Veterinarian (IIC).

- ◆ In two establishments, there was inadequate monitoring and documentation, by field NFA officials, of the establishment's fulfillment of their responsibilities regarding the requirements for HACCP systems and, in one of these, also regarding the requirements for SSOP'S.

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 on September 27, 2002 in Helsinki. At 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

The individual Foreign Establishment Audit Forms are attached on the following pages.

Dr. Gary D. Bolstad
International Audit Staff Officer
Program Evaluation, Enforcement, and Review

REVIEW DATE
 Sept. 10, 2002

NAME OF FOREIGN LABORATORY *AH.B-1a*
 Atria Oyj

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 National Food Agency provides oversight
 of this private lab in Establishment 22

CITY & COUNTRY
 Nurmo, Finland

ADDRESS OF LABORATORY
 Nurmo

NAME OF REVIEWER
 Dr. Gary D Bolstad

NAME OF FOREIGN OFFICIAL
 Dr. Eija Laikko

Residue Code/Name		Sal	Ecol													
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		C	C											
	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	C												
	Correct Tissue(s)	08	O	O												
	Equipment Operation	09	O	O												
	Instrument Printouts	10	O	O												
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O	O												
	Recovery Frequency	12	O	O												
	Percent Recovery	13	O	O												
	Check Sample Frequency	14	O	O												
	All analyst w/Check Samples	15	O	O												
	Corrective Actions	16	O	O												
	International Check Samples	17	O	O												
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O	O												
OTHER REVIEW		19														
		20														

SIGNATURE OF REVIEWER

GD Bolstad

DATE

9/10/02

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE Sept. 10, 2002	NAME OF FOREIGN LABORATORY Atria Oyj	B-1b
FOREIGN GOV'T AGENCY National Food Agency provides oversight of this private lab in Establishment 22		CITY & COUNTRY Nurmo, Finland	ADDRESS OF LABORATORY Nurmo	
NAME OF REVIEWER Dr. Gary D Bolstad		NAME OF FOREIGN OFFICIAL Dr. Eija Laikko		

RESIDUE	ITEM	COMMENTS
Sal	01	NFA officials perform the swab sampling for <i>Salmonella</i> species. According to information provided to FSIS by NFA, establishment employees take the samples under the supervision of NFA.
E coli	01	Establishment personnel performing a gauze pad for generic <i>E. coli</i> , under the supervision of the in-plant NFA officials. According to information provided to FSIS by NFA, NFA officials perform the swab sampling.
Sal	02	Sampling is directed by the EELA laboratory according to Finnish law. For 2002, 650 sows and 730 pigs are sampled (swabs and lymph nodes) for <i>Salmonella</i> .
E coli	02	In this establishment, one carcass in 5,000 is sampled for <i>E. coli</i> for the U.S. requirements; on one day per week, 5 samples are also taken for an EC requirement that has been included in Finnish legislation. This establishment slaughters an average of 2,100 swine per day.
Sal	07	This laboratory is now using the ISO 6579 (1993) method, which was accepted as equivalent for the information included in the 12/20/99 public meeting on foreign country equivalence.
E coli	07	The method used for <i>E. coli</i> is NMKL Method No. 147 (1993), <i>Coliform Bacteria and Escherichia coli in Foods</i> . This method has been submitted to FSIS for an equivalence determination and a decision on its equivalence is pending as of the time of this audit.
Sal	07	The sampling sites for <i>Salmonella</i> include the sites used for <i>E. coli</i> , which are in compliance with FSIS requirements.

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 Sept. 19, 2002

NAME OF FOREIGN LABORATORY *A.H. B-2a*
 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
 Ms. Seija Berg, Acting Director; Dr. Eiga Jaikko, Sr. Ofcr, Food Control

Residue Code/Name			chc	pcb	abc	cap	tet	cc	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	C	A	A	A			
	Timely Analyses	03	A	A	A	A	A	A	A	A	A	A			
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O			
	Interpret Comp Data	05	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	A			
	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	C	A	A	A	A			
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A	A			
	Corrective Actions	16	C	C	C	C	C	C	C	C	C	C			
International Check Samples	17	A	A	A	A	O	O	A	O	O	A				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O	O	O	O	O	C	O	O	O	O			
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER

GD Bolstad

DATE

9/19/02

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE Sept. 19, 2002	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 Ms. Seija Berg, Acting Director; Dr. Eiga Laikko, Sr. Ofcr, Food Control	

RESIDUE	ITEM	COMMENTS
		Abbreviations: chc = chlorinated hydrocarbons, abc = antibiotics cap = chloramphenicol, tet = tetracyclines, des = diethylstilbestrol, sul = sulfonamides, and ivm = ivermectin.
TE		According to the 2002 national residue testing plan, meat samples are analyzed for lead and cadmium; milk samples are analyzed for arsenic and mercury.
TET		The national residue testing plan does not call for any meat samples to be tested for tetracyclines, only samples from broiler chickens and eggs.
OP	02	With one exception, no organophosphates have been detected in field samples for the past eleven years: there was one violative sample in the past year, for phoxim, an anthelmintic, in a sow. The 2002 national residue testing plan includes 30 samples from sows (specifically for phoxim) and five samples from bovines for OPs in general.
All	06	Violative results are reported immediately to the NFA authorities both in the central headquarters and in the establishments of origin. Routine, negative results are reported annually.
des,sul	08	The following tissue matrices were used: for DES - urine and feces, and for sulfonamides - muscle
All	16	Supervising chemists in charge of the various departments were responsible for determining the causes of unexpected results, but there were no actual written corrective action programs <i>per se</i> to be followed in the event that an analyst's performance did not meet expectations. The laboratory management personnel agreed to incorporate such a written corrective action program in their quality assurance procedures promptly.
OP	18	Only one intra-laboratory check sample was being run per year for organophosphates. None were done in 2001. Positive, spiked internal standards were being run with each sample; two sample sets were being run per year. (FSIS expects monthly check samples to be run, even if field samples are not analyzed monthly.) The acting laboratory director said this would be initiated immediately.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Atria Oyj Kuopio	2. AUDIT DATE Sept. 13, 2002	3. ESTABLISHMENT NO 10	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	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	X
29. Records		57. Monthly Review	X
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Att. A-1b

60. Observation of the Establishment

- 13a The documentation of pre-operational sanitation activities was not performed as required in the written plan, and corrective actions were not adequately described.
- 13b The "weekly" documentation of operational sanitation activities had not been documented at all during two weeks over the course of the past 2 months. FSIS requires *daily* documentation of operational sanitation activities.
- 22a The in-plant NFA personnel and the slaughter foreman were usually *not* notified in writing (or even orally) when fecal contamination was found at the pre-boning trim stations, as part of the required corrective actions in the establishment's written HACCP program. See also the comments under 46d, below.
- 22b 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. No effective preventive measures had been taken to correct the problem.
- 28 The sampling procedure for generic *E. coli* was demonstrated. The laboratory technician's technique for handling of gloves and collection tools was not aseptic, and she handled various other areas of the carcass with her "sterile" gloves between sampling sites.
- 34 No species verification was being performed in this establishment (or in any other establishment in Finland). This was a repeat finding. NFA had applied to IPS for an exemption, but none had as yet been granted. NFA officials were preparing a species verification program, to be proposed to FSIS and implemented before the country exit meeting on September 27.
- 39a No hand soap dispenser was provided at the beef evisceration station. NFA officials ordered correction.
- 39b/56 One of the two sterilizers at the swine evisceration station was practically empty, but was being used by the operators. This was corrected promptly.
- 39c Maintenance of over-product structures had been seriously neglected in several areas of the establishment. Some corrective actions were taken; others were planned.
- 40/56 European Community Directives require 540 Lux (49 foot-candles) of light at inspection stations. 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. Corrective actions were taken promptly.
- 41/46/51/56 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. This was a repeat finding.
- 45 Several stainless combo bins being used for product, were cracked and in need of repair. They were removed promptly.
- 46a Fecal contamination of beef carcasses presented for post-mortem inspection was a common occurrence. Although some feedback was provided by the inspectors to the establishment personnel, preventive measures had been ineffective.
- 46b 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. No immediate corrective actions were taken.
- 46c 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.
- 47a/56 Several slaughter employees were observed to fail to wash their hands after contaminating them before continuing operations. This was a repeat finding. NFA officials ordered corrective actions.
- 47b Maintenance workers, called to fix an over-product structure problem, set up their ladder directly adjacent to exposed carcasses hanging in the quartering area. The NFA officials ordered them to stop while the exposed product was removed from the area.
- 51 Monitoring by the in-plant NFA officials of establishment compliance with HACCP and SSOP requirements was inadequate.
- 55/56 A swine carcass that had not been split, yet bore the marks of inspection, was found in a cooler (the mandibular lymph nodes had been incised). The inspection personnel were unable to offer an explanation. (Both EC Directives and USDA regulations require that carcasses must be split before being presented for post-mortem inspection.) The carcass was condemned by the Chief Official Veterinarian (IIC).
- 57 No internal reviews had been conducted in November 2001 or January 2002; according to NFA officials, internal reviews had been conducted in December 2001 and March 2002, but no written reports had been generated.

The NFA officials determined that the establishment failed to meet U.S. requirements and voluntarily removed it from the list of establishments eligible to export to the United States, effective as of the start of operations on the day of this audit.

Accompanying NFA officials: Dr. Marjoriikka Keränen and Dr. Eero Laikko, Senior Veterinary Officers; Dr. Riitta Mustonen (Provincial Veterinarian, internal reviewer); and Dr. Sakari Hietakorpi, Chief Official Veterinarian (in charge of Est. 10)

61. NAME OF AUDITOR

Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

[Handwritten Signature] 9/13/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Ruokatalo OY Teollisuuskatu 17 Forssa	2. AUDIT DATE Sept. 5, 2002	3. ESTABLISHMENT NO 18	4. NAME OF COUNTRY Finland
	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input 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	X
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/Laboratories	
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

Att. A-2b

- 34 No species verification was being performed in this establishment (or in any other establishment in Finland). This was a repeat finding. NFA had applied to IPS for an exemption, but none had as yet been granted. NFA officials were preparing a species verification program, to be proposed to FSIS and implemented before the country exit meeting on September 27.
- 39 There was no hand soap dispenser at one post-mortem inspection station (external carcass inspection) or for the person in the edible offal room harvesting esophagi, and the hand-soap dispenser for the inspector incising and observing mandibular lymph nodes was not conveniently located. New hand-soap dispensers were installed promptly during the next break (within 30 minutes of being identified).

Accompanying NFA officials: Dr. Anna-Maija Grönlund, Senior Veterinary Officer; Dr. Inna Ilivitzky, Provincial Veterinarian; Dr. Juhani Koivumäki, Chief Official Veterinarian

61. NAME OF AUDITOR

DR. GARY D. BOLSTAD

62. AUDITOR SIGNATURE AND DATE

GDBolstad:MN 9/5/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Atria Oyj Nurmo	2. AUDIT DATE 9/9/002	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	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
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	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Att. A-3b

34 No species verification was being performed in this establishment (or in any other establishment in Finland). This was a repeat finding. NFA had applied to IPS for an exemption, but none had as yet been granted. NFA officials were preparing a species verification program, to be proposed to FSIS and implemented before the country exit meeting on September 27.

45 Many stainless steel combo bins, in use for edible product, had cracked and torn edges, and were in need of repair or replacement. This deficiency had been identified during the previous FSIS audit in August 2002. The NFA officials ordered the establishment management to conduct an inspection of all such containers, repair or replace those that were deteriorated, and develop and implement a more effective program for monitoring their condition. The management officials ordered several dozen new containers, before the day was over, and gave assurances that the irreparable ones would not be used for edible product.

55/56 An un-split sow carcass observed in a cooler, on the rail reserved for thermal processing (all carcasses from sows are sent to thermal processing); the mandibular lymph nodes had not been incised and inspected. Due to a misunderstanding at the side rail, one post-mortem inspector had thought that another inspector had conducted post-mortem inspection on the carcass and had marked it with the official mark of inspection. Both European Community and FSIS regulations require splitting of the carcass before post-mortem inspection and incision and observation of the mandibular lymph nodes as part of the post-mortem inspection procedure. The Veterinarian-In-Charge identified the oversight, condemned the carcass immediately, and gave assurances that he would discuss the matter with the inspection staff to avoid any similar occurrence in the future.

Operations: Swine slaughter, pork cutting and boning, and (not for U.S. export) convenience foods, cooked sausages.
 Exported to the U.S.: Pork loin back ribs and spare ribs, and casings. One shift, swine slaughter only, production volume average 10,500 per week.

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

[Signature] *9/9/02*

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Oy Snellman Ab Pietarsaari	2. AUDIT DATE Sept-11-2002	3. ESTABLISHMENT NO 62	4. NAME OF COUNTRY Finland
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input 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		X
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 SSOPs have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		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.		X	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		X
24. Labeling - Net Weights			52. Humane Handling		
25. General Labeling			53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection		
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		
27. Written Procedures			Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis			56. European Community Directives		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

Att. A-4b

- 22 The establishment's written procedure for preventive measures, to be taken when visible contamination with ingesta is found after the critical control point for zero tolerance, was not followed. This procedure included written notification of the cutting room foreman, the quality control manager, and the slaughter foreman. On the day of the audit, the pre-boning trimmer had documented 4 instances of visible contamination with ingesta on carcasses entering the cutting room; the contamination had been trimmed, but no feedback had been provided as required. A document review indicated that, over the course of the past month, contamination with ingesta had been documented on twelve days, and the required written notification had not been provided. One beef quarter that had passed the pre-boning trim station was found with a small area of visible contamination with ingesta on the day of the audit; it was trimmed, and all other quarters in the cutting were ordered by the NFA officials to be reinspected (no further visible contamination with ingesta was found).
- 34 No species verification was being performed in this establishment (or in any other establishment in Finland). This was a repeat finding. NFA had applied to IPS for an exemption, but none had as yet been granted. NFA officials were preparing a species verification program, to be proposed to FSIS and implemented before the country exit meeting on September 27.
- 39 There was no hand soap dispenser at the main pre-boning trim station. This was corrected on the day of the audit.
- 46/56 Pre-operational sanitation inspection by the Inspector-In-Charge was observed. Roller trolleys for edible product containers were found to be not clean before the start of operations, and were stacked, with their wheels in contact with the upper surfaces of those below. The undersides of cutting boards were not adequately cleaned before use. Plastic bags for product-contact were stored in plastic containers that were not adequately clean. The NFA officials ordered all the above to be re-cleaned before the start of operations, and written notification of the deficiencies was provided to the cleaning company.
- 46 Several white plastic containers, intended for edible product, were found to be used for other purposes, without being labeled appropriately. The Veterinarian-In-Charge ordered all these containers to be immediately labeled for use only for inedible materials.
- 51 Monitoring by the in-plant NFA officials of establishment compliance with HACCP requirements was inadequate.

All deficiencies noted during the previous FSIS audit in August 2001 had been corrected, with the single exception that no internal review had been conducted in December 2001.

Following this audit, the NFA officials agreed to issue an official letter to the establishment management requiring that the deficiencies identified on the day of the audit must be corrected, and preventive measures implemented to ensure continuing compliance, within 30 days of the day of the audit, or the establishment would be removed from the list of establishments eligible to produce product for U.S. export.

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. Osmo Mäki-Petäys, Dr. Marjoriikka Keränen, Dr. Riita Mangs

61. NAME OF AUDITOR
Dr. Gary D. Bolstad

62. AUDITOR SIGNATURE AND DATE

GD Bolstad

9/11/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HK Roukatalo Oyj/Pakastamo Oy 01511 Vantaa	2. AUDIT DATE Sept. 6, 2002	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	X
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.		X	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/Laboratories	
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	X
Salmonella Performance Standards - Basic Requirements			58.	
30. Corrective Actions		O	59.	
31. Reassessment		O		
32. Written Assurance		O		

60. Observation of the Establishment

Att. A-5b

- 13 Establishment personnel were documenting daily pre-operational sanitation activities, findings, and corrective actions, but operational sanitation activities were documented only when problems were found. The management officials now gave assurances that they understood the requirement and would implement daily documentation of operational sanitation activities; the attending NFA officials gave assurances they would monitor compliance.
- 34 No species verification was being performed in this establishment (or in any other establishment in Finland). This was a repeat finding. NFA had applied to IPS for an exemption, but none had as yet been granted. NFA officials were preparing a species verification program, to be proposed to FSIS and implemented before the country exit meeting on September 27.
- 57 There had been no documented monthly supervisory visits for October 2001, January 2002 (due to vacation of the reviewer), or July 2002 (vacation again). An additional internal reviewer has been added to the staff, as of Sept. 2, 2002.

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

Accompanying NFA personnel: Dr. Marjoriikka Keränen, Senior Officer; Dr. Kirsi Saario, Provincial Veterinarian; Dr. Irma Etelämäki, Official Veterinarian (in charge)

61. NAME OF AUDITOR

DR. GARY D. BOLSTAD

62. AUDITOR SIGNATURE AND DATE

[Signature] *9/6/02*

February 3, 2003

2360/505/02

Sally Stratmoen
Chief, Equivalence Section
International Policy Staff
Office of Policy, Program Development and Evaluation
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington D.C. 20250
USA

Dear Dr. Stratmoen

Ref: Your letter, November 27, 2002

Subject: **AUDIT REPORT FOR FINLAND, SEPTEMBER 3 – 27, 2002**

The National Food Agency (NFA) has the following comments as regards audit report, 2002:

6 Main findings

6.2 Government Oversight

Second sentence should read: Activities of the NFA *and the Plant Production Inspection Centre* cover all foodstuffs from field to table.

Third sentence: The right term is *provincial state offices*, not provincial governments.

6.2.1 CCA Control Systems

First paragraph:

Third sentence should read: This unit is also responsible for *some* tasks under the Act on the Implementation of the Common Agricultural Policy. (The Milk and Egg Hygiene Unit has also tasks related the above mentioned Act.)

Fourth sentence: The unit develops the uniformity and efficacy of food control *in its own area*.

Last sentence: The Product Authority for Welfare and Health is an unknown authority. The institute referred to is probably the Plant Production Inspection Centre.

Second paragraph should read: *The Ministry of Agriculture and Forestry transposes all relevant EU legislation into Finnish law.*

6.2.3. Assignment of Competent, Qualified Inspectors

Third sentence should read: They must then pass specific examinations before being qualified to work in *full throughput* establishments. (The word export establishment is inaccurate because it is used e.g. in 13.4 in the meaning "establishments eligible for export to the USA".)

11.3 Testing for generic E.coli

The NFA requested on April 8, 2002 that, in addition to government inspectors, also establishment employees could take the samples. This would be in accordance with the US domestic requirements. Equivalency has not yet been granted.

13.2 Testing for *Salmonella* species

First paragraph:

There is an error in the eighth bullet point. It is stated that sampling of two large sites is regarded as equivalent. This is true as regards cattle, but not as regards pigs. Samples are taken also from the jowl area of pigs which was a requirement of the FSIS in connection with the equivalency negotiations on *Salmonella*.

Third paragraph:

First bullet point: As far as we understand, one of the meanings of swab is gauze. In addition, in the equivalence determinations of FSIS on March 23, 1999, it is stated the following: "Separate swabs (10 cm x 10 cm pads) are used per site ..." Furthermore, the term gauze is used several times in the letter of the EELA on the sampling for *Salmonella* testing (December 21, 1998). Based on the above mentioned, we regard that the use of gauze pad was recognized as equivalent.

Second bullet point: The NFA requested on April 8, 2002 that, in addition to establishment employees, also the government inspectors could take the samples.

Third bullet point: Testing of samples individually does provide as accurate information on *Salmonella* as composition of samples. Please note also that the prevalence of *Salmonella* in pigs is practically zero in Finland. More information on the extensive Finnish *Salmonella* control program can be acquired in the following web site www.mmm.fi/el/julk/zoonrap/en.html

Fourth bullet point is erroneous: None of the establishments used NAKL method for *Salmonella* during the audit. The NFA personnel accompanying the USDA auditor confirmed that the ISO method was in use in the establishments.

13.4 Monthly reviews

Second paragraph: A strong emphasis is placed on meat hygiene during the *fourth* year of the six year education.

Sixth paragraph: There is a reference to the EELA in the last sentence. It should be amended to refer to the NFA.

Eighth paragraph: In the last sentence there is an erroneous reference to a NFA official. The official in question was a provincial veterinary officer, and all the provincial officers are employed by the Ministry of Internal Affairs, not the NFA.

Yours sincerely

Osmo Mäki-Petäys
Director
Meat and Fish Hygiene Unit

Anna-Majja Grönlund
Senior Officer
Meat and Fish Hygiene Unit