United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR FINLAND

SEPTEMBER 18 – OCTOBER 3, 2000
May 24, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Finland's National Veterinary and Food Research Institute's (EELA) Meat and Fish Hygiene Unit from September 18 – October 3, 2000. Seven establishments certified to export meat product to the United States were audited. Six were slaughter and processing establishments and one was a cold store/freezer facility.

The last on-site audit of Finland's inspection system was conducted in September 1999. At that time, seven establishments were certified to export meat product to the United States; six were audited: three (Est. 18,22, and 6472) were rated acceptable, two (Est. 74 and 78) were rated marginally acceptable (recommended for re-review), and one (Est. 10) was evaluated unacceptable (removed from export eligibility). Among the deficiencies observed in these establishments, and the national residue testing laboratory were:

- Inadequate antemortem and/or postmortem inspection procedure in establishments 10, and 78, inhumane handling of animals (Est. 10), and inadequate lighting at inspection stations in Establishments 10, 18, and 78.
- Product contamination due to inadequate sanitizing of common contact between carcasses and equipment in Establishments 10, 18, 74, and 78; product contamination with feces, ingesta, grease, hair, condensation, floor contact, inadequate sanitizing or rinsing contaminated knives or hands, storage under leaky ceilings, and failure to separate containers for edible and inedible product in Establishments 10; inadequate pre-boning trim and/or inadequate boneless reinspection in Establishments 10, and 78; insanitary carcass dressing procedures in Establishment 78; and poor personal hygiene in Establishments 10, 18, and 74.
- Poor maintenance of facilities and equipment in Establishments 10, 18, 22, and 78.
- Incomplete and/or inadequate description of operational sanitation program in written SSOPs in Establishments 10, 18, and 62. Deficient documentation of pre-and/or operational sanitation activities, corrective actions and preventive measures in Establishments10, 22, 62, and 78. Inadequate oversight documentation by inspection service officials for Sanitation Standards and Operating Procedures (SSOPs) and Hazard Analysis and Critical Control Points (HACCP).
- Failure to randomly select carcass for generic *Escherichia coli (E. coli)* and *Salmonella* testing, failure to identify designated sample collection location (Est. 22 and 62), and failure to record test results on a process control chart showing 13 most recent test results for *E*. coli (Est. 62).

- Residue testing laboratory performance deficiencies, such as failure to analyze samples within required turn-around time, and failure to meet required quality standards for intra-laboratory check samples, and acceptable recoveries.
- Failure to conduct species verification testing.

The auditor, during this audit, verified that all of the above deficiencies had been corrected.

During January to August, Finland exported 1,574 pounds of pork product to the United States. At the U.S. port of entry on reinspection 43,067 pounds were rejected labeling, and transportation damage defects.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with various Finland's meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed discussions and audit of inspection system control documents at the headquarters. The third included on-site visits to seven establishments certified to export to the United States. The fourth was a visit to three laboratories performing analytical testing of samples for the national residue and microbiological monitoring program, testing *Salmonella* species, and testing generic *E. coli*.

Finland's program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Finland's inspection system was assessed by evaluating these five risk areas.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary:

At the time of audit, all establishments (10, 18, 22, 62, 74, 78, and 6472) visited were acceptable. However, following deficiencies were noted:

The in-plant inspection staff lacked PR/HACCP training, and did not fully comprehend the monitoring and verification of the process control aspects.

In cut-up and boning operations of Establishments 10, 18, 22, 62, 74, and 78, the procedures for incidentally dropped meat were inadequate. Immediate corrective actions were taken by the establishment to preclude likely product contamination or adulteration.

In Establishments 22, 62, 74, and 78 condemned/inedible product and dead on arrival (DOA) carcasses were not denatured or decharacterized.

Establishments 18, 22, 62, 74 and 78 did not use process control technique (charting or plotting the results overtime) for generic *E. coli* to determine what variation in test results was within normal limits. The normal limits for sponging technique were not established.

Finland's national *Salmonella* species testing program determined equivalent to U.S. system was satisfactory. It was stated that establishments, which continued to fail U.S. required performance standards, could be removed from eligibility to export to United States.

Testing for arsenic and mercury residues was not being done.

Entrance Meeting

On September 18, 2000, an entrance meeting was held at the EELA office in Helsinki and was attended by Dr. Osmo Mäki-Petäys, Head Department of Food Control, Dr. Anna-Maija Grönlund, Senior Veterinary Officer, and Dr. Tiina Laitala, Senior Veterinary Officer, and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS, Field Operations. Topics of discussion included:

1. Audit itinerary.
2. Use of nutritional or geographic claim labels.
3. Effective implementation of sanitation, facilities and equipment.
4. Deficiencies in conducting in laboratory quality assurance program.
5. Performances deficiencies in conducting proper postmortem inspection procedures.
6. Oversight and verification of PR/HACCP.
7. FSIS policy on 'listing and delisting' of establishments.

Finland's inspection system officials stated that deficiencies noted during previous FSIS audit had been properly addressed and effective control measures had been taken to prevent recurrence of these deficiencies.

Headquarters Audit

There had been no changes in staffing or inspection system organization since the last U.S. review of Finland's meat inspection system in September 1999.

To gain an accurate overview of the effectiveness of inspection controls, the FSIS auditor requested that the audits of the individual establishments be lead by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of the inspection system documents that included:

- Internal audit reports.
- Label approval records such as generic labels.
- Laboratory quality assurance programs including audit of documents on handling of samples, analytical procedures and results, review and corrective actions taken for deviations or errors (equipment and personnel proficiency checks), and maintenance of records.
- Food safety initiatives such as SSOP, HACCP programs generic *E. coli* testing, *Salmonella* testing, *Listeria monocytogenes* testing, and species testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Epidemiology and zoonotic trends in Finland including control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.

Significant findings have been discussed under appropriate headings in this report.

The CY 2000 EELA training Program was reviewed. Several continuing education courses for veterinarians, food inspectors (auxiliaries), laboratory staff, and management/supervisors are offered annually. A publication on courses offered was available. The courses were designed to update education on food safety, laboratory procedures, management and leadership, regulatory changes and new or developing food safety initiatives.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by EELA as eligible to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel.

Establishment Audits

Seven establishments (10, 18, 22, 62, 74, 78, and 6472) were certified to export meat products to the United States. With the exceptions described in the text, generally the inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

On September 2l, 2000, the auditor visited the municipal Food and Environmental Laboratory in City of Vantaa; on September 25 he visited a private laboratory in Forssa; on September 27, 2000, the auditor reviewed National Veterinary and Food Research Institute in Helsinki; and on October 2 he visited the Regional Laboratory in Kuopio. The laboratories were well equipped and staffed with competent and highly qualified staff.

The Veterinary and Food Department of the Ministry of Agriculture and Forestry prepares legislation on concerning animal health and related maters including animal health, food stuffs of animal origin and the administration and general services. The National Veterinary and Food Research Institute (EELA) under the Ministry of Agriculture and Forestry determines and documents animal diseases, conducts research and education, and monitors the quality and safety of food of animal origin. It directs and supervises the official control of food of animal origin. The Institute develops national residue control plans for food of animal origin, for implementing the plans, and for collecting data and results.

On September 27, 2000, the auditor visited EELA. It is also the national reference laboratory for residue analysis of food of animal origin. It comprises the Department of Food Control, Department of Chemistry, Department of Food Microbiology, Department of Bacteriology, Department of Pathology and Field Extension, Department of Virology and Epidemiology, and Administration.

The Department of Chemistry is the national reference laboratory, and performs chemical analysis of the residue control plan for meat, poultry, fish, milk, eggs and honey, except coccidiostatic tests, some organophosphates and dioxin analyses. Coccidiostatic analyses for meat and poultry is conducted in the Agricultural Chemistry Department of the Plant Production Inspection Center; carbamates, prythroid and chlorinated hydrocarbon compounds analyses of honey, and organophosphates of milk and honey is done by the Custom Laboratory of the National Board of Customs under the Ministry of Finance; dioxin, PCDD, PCBs and non-ortho PCBs from milk and human tissues, soil and sediments.

The Department of Microbiology is the national reference laboratory for microbial/anti-microbial tests, planning of annual residue control programs for food of animal origin in collaboration with Department of Food Control and Department of Chemistry.

Additionally, there is a network of public laboratories and authorities related with the national reference laboratory EELA. There are five Provinces with a veterinary staff of 16 officers in 12 offices. There are 249 municipal (equivalent of a U.S. county) food control authorities and 50 municipal food control laboratories staffed with 388 veterinarians, 426 health inspectors, 56 chemists and microbiologists and 350 full-time and part-time veterinarians laboratory technicians. There are three EELA regional laboratories for diagnosis on animal diseases in Kuopio, Oulu, and Seinajoki.

On September 26, 2000 the auditors visited a private laboratory testing generic *E. coli* and *Salmonella* species. The microbiological anti-microbial tests are carried out in slaughterhouses'

owned laboratories and/or at the municipal food control laboratories. These are Atria Oy, Kauhajoki, Atria Oy, Kuopio, Atria Oy, Nurmo, Lahtiteurstamo Oy, Lahti, HK Ruokatalo, Forssan Labratorio, Forssa, OT Karjaporti, Lappeenranta, Pouttu Oy, Lihantarkastuslboratorio, Kannus, Pouttu Foods Oy, Outkumpu, and Snellmanin Teurastamo Oy, Pietarsaari.

There are 50 Municipal Food and Environmental laboratories nationwide. Municipal laboratories operate under Food Act, the Hygiene Act, and the Health Protection Acts. On September 28, 2000, the auditor visited one of the Food and Environmental Laboratory in city of Vantaa, which is approved by the National Food Administration, and National Veterinary and Food Research Institute (under Hygiene Act), and animal diseases, and accredited by Finish Accreditation Service (FINAS) for 62 methods for microbiological and chemical testing of food and water including Salmonella. The laboratory routinely test food samples, especially food borne pathogens, molds, heavy metals, water, and the environment. The laboratory is financed with public funds, and levies service-fees from privately requested samples. The lab serves a municipality (equivalent of U.S. county) of 170,000 citizens, and analyzes about 60,000 samples annually. It operates under the local government of the municipality of Vantaa. The municipality has four veterinarians.

When a positive result for *Salmonella* species is found and confirmed, EELA requests provincial government to initiate investigation, and if violation is confirmed, it is pursued with legal punitive proceedings.

There are about 250 municipal food authorities in the country. The municipal and provincial executives are political appointees. The provincial authority directs the municipality veterinar1ans to follow up and make recommendation for disposition of the case.

Finish Accreditation Service (FINAS) in Helsinki accredits all laboratories authorized to analyze regulated substances. FINAS is a national accreditation body, which is part of the Center for Metrology and Accreditation under the Ministry of Trade and Industry. It offers accreditation services to the laboratories, inspection, and certification bodies. It follows the requirements of the European Standards and Guidelines

During the laboratory audits, emphasis was placed on application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Inter-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The deviations noted during the previous FSIS audit in September 1999 had been corrected. Effective controls were in place for sample handling and frequency, data reporting, equipment operation and printouts, minimum detection level, recovery frequencies, and percent recoveries. Analytical methods used were EU or EELA approved, and validated.

Establishment Operations by Establishment Number

The following operations were being conducted in the establishments visited:

10 - Beef, pork, and lamb slaughter, cut up, boning, and dry sausage production
18 - Swine and lamb slaughter, cutup, and boning
22 - Swine slaughter, cutting and boning
62 - Swine, beef and lamb slaughter, cut up, boning, and sausage production
74 - Beef and lamb slaughter, cut up and boning
78 - Beef slaughter, cut up and boning
6472 - Cold store/freezer

SANITATION CONTROLS

Based on the on-site audit of establishments, Finland's inspection system had controls in place for back-siphonage prevention, separation of establishments, temperature control, operations and inspectors' work space, ventilation, approval of facilities and equipment, welfare facilities, outside premises, personal dress and habits, product reconditioning and transportation, operational sanitation, and waste disposal.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

Sanitary Dressing

In Establishments 62 and 74, the carcass head-wash cabinets were poorly designed resulting in actual or potential cross contamination. The establishment took immediate measures to eliminate product cross contamination during the audit. It was stated that the facilities and equipment changes would be made immediately to improve procedures and to eliminate actual or potential cross product contamination.

ANIMAL DISEASE CONTROLS

Official records of the Ministry of Agriculture and Forestry on 'Zoonosis in Finland 1999', and 'Animal Diseases and Animal Welfare in Finland' were audited. In 1999, Finland had been free of animal diseases of listed in published by International Office of Epizootics (OIE) in list A, and B including BSE. No significant cases of zoonotic importance had been reported.

The auditors also determined that the Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) requirements for animal health had been met.

RESIDUE CONTROLS

On September 26, 2000, the auditor visited EELA's National Veterinary and Food Research Institute's laboratories complex in Helsinki, discussed Finland's national residue monitoring and control program, and audited official records on Quality Assurance program, analytical results, and laboratory records, and equipment performance, etc. The annual residues testing plan was satisfactory. The official records indicated:

- As of September 790 samples had been analyzed for chlorinated hydrocarbons including PCB's, hormones including DES, sulfas, clenbuterol. However, targeted samples for organophosphates and nitrofurons had not been sampled. It was stated that these samples were planned to be collected and would be analyzed in the third quarter.
- Samples for hormones analyzed (immuno-chemical screening) as of September 18, 2000) – 747 out of 1285 samples in meat and poultry.
- Samples for trace element (cadmium and lead) residues analyzed (as of September 25, 2000) - 232 muscle, liver and kidney samples of 245 collected. Arsenic and mercury elements were not included in CY-2000 plan.

The audit of Finland's residues testing results for meat and poultry in 1999 indicated that there were three samples positive for veterinary drugs, two samples positive for mycotoxins in swine, and two samples in elk, and 111 samples in reindeer. The residue testing results as of September 25, 2000 indicated that one sample was positive for sulfas.

Following officials discussed Finland's National residue control plan and sampling and related laboratory procedures:

Professor Dr. Timo Hirvi, Head of the Department of Chemistry,
Dr. Anna-Liisa Myllyntemi (Microbiological Residues Testing),
Dr. Ulla Perttila (Immuno-Chemical screening, and other contaminants),
Erja Lintfors (Liquid Chromatography of Anti-microbial Residue Control and Sampling Plan),
Seija Berg (Pesticides, and Hormones and in-charge of Laboratory Quality Assurance Program),
Eija-Riitta Venalainen (Trace Elements), and
Dr. Anne Fagerlund (Coordination Staff National Residue Control Program.

Th staff offered documentation and explanation in response to findings cited in previous FSIS audit in September 1999, as follows:

- *Samples analysis time – greater than FSIS-Labs turn-around time*. It was stated that some of the compounds and elements such as trace elements and chlorinated hydrocarbons were very stable and three to four week turnaround time instead of 2-weeks FSIS standard, and was not a not a significant factor. The turn-around periods were consistent with Finland's national Laboratory Quality Assurance Program.
- *Matrices (organs, tissue) used for analysis – dissimilar than used by FSIS-Labs*. Kidneys were used for antibiotics screening, and muscle was used for analyses of sulfas, tetracycline and chloramphenicol; fat was used for analyses of organophosphates for convenience and for being as sensitive as fat and liver both; and muscle was used for screening of sulfas with a

modified and validated (*published) HPLC method instead of liver; and for analyses of hormones in live animals, the matrices used were urine, feces, blood and hair, and liver, muscle, urine and blood from slaughtered animals. These methods and matrices were consistent with Finland's national Laboratory Quality Assurance Program.

- *Chlorinated hydrocarbons recoveries – lower than FSIS-Labs*. Finland uses a batch of 15 different chlorinated hydrocarbons, some of which are highly volatile; therefore recoveries in these batches were consistently between 60% to 100%. These recoveries were consistent with Finland's national Laboratory Quality Assurance program.
- *Intra-laboratory checks sample program – dissimilar to FSIS-Labs.* The intra and interlaboratory check sample program was consistent with Finland's national Laboratory Quality Assurance program.

HACCP Implementation

All establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

The in-plant inspection staff had not been formally trained in SSOPs and HACCP. The inspectors needed training to grasp oversight, verification and compliance enforcement of the PR/ HACCP systems.

Testing for generic *E. coli*

The slaughter establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment C). The following concerns arose during the audit:

Except for Establishment 10, other establishments (18, 22, 62, 74, and 78) did not establish normal limits for generic *E. coli* using surface-sampling method. These establishments erroneously used 'm and M' limits for excision method, and failed to use process control technique (charting or plotting the results overtime) to determine what variation in test results *(E. coli*) was within normal limits.

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* Aerts, M.M.L., Beek M.J., and Brinkman, U.A. Th.: Monitoring of veterinary drug residues by a combination of continuous flow technique and a column-switching high-performance liquid chromatography: I. Sulphonamides in egg, meat and milk using post-column derivatization with dimethylaminbenzaldehde. *J. Chromatograpghy*, 435 (1988) 97-112.

ENFORCEMENT CONTROLS

Inspection System Controls

The Finish inspection system performs, at least, monthly in-depth reviews of U.S.-certified establishments. The establishment's system conducts boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product. However some of the serious deficiencies noted were:

- In all slaughter and cut up/boning operation establishments (10, 18, 22, 62, 72, and 78) facility, equipment, and procedures for incidentally dropped meat were inadequate to prevent or eliminate product contamination or adulteration.
- In all slaughter and processing establishments dead on arrival (DOA) carcasses were not denatured or decharacterized before off-premises shipment.
- Condemned or inedible product was not destroyed, denatured or decharacterized before off-premises removal in Establishments 22, 62, 74, and 78.
- Dressing facility, equipment and procedure for swine heads preparation for inspection in Establishment 74 were inadequate resulting in actual and/or potential cross contamination of the product.

RESIDUE CONTROLS

On September 16, mesenteric lymph nodes collected from a swine carcass in Establishment 22, tested positive for *Salmonella* in private approved laboratory in Forssa. The official veterinarian-in-charge reported results to provincial veterinary authority, and sent materials to the relevant Municipal reference laboratory in Turku for confirmation. The samples were determined negative. However, the municipal field veterinarian investigated at the farm of origin, and collected 59 feces samples from sows and market hogs; the samples were analyzed and found negative; the results were sent to the authorities; and the case was closed.

The residue testing results as of September 25, 2000 indicated that one sample was positive for sulfas. The respective provincial and municipal authorities were asked to collect additional samples from the farm, and conduct on-site investigation of the incidence. The follow up investigation was in progress.

Testing for *Salmonella* Species

Finland has adopted an equivalent *Salmonella* testing program, which has been in place for several years. All slaughter establishments in Finland that were audited were required to meet national *Salmonella* monitoring program requirements and comply with FSIS testing procedures. Basic FSIS regulatory requirements were evaluated according to the criteria employed in U.S. domestic inspection program.

The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* sampling and testing was being conducted according FSIS evaluated procedures for equivalence, and routinely tested in national accredited private laboratories. The suspicious samples were screened in municipal accredited laboratories, and strain typing is done by national Food Microbiology reference laboratory in Helsinki.

No deviations were observed during the audit.

Testing for *Listeria monocytogenes*

It does not apply. Currently ready to eat product is not prepared for U.S. market.

Species Verification Testing

At the time of this audit, Finland was not exempt from species verification-testing requirement. EELA had implemented the new procedure, which required the inspectors to collect samples from each lot prior to shipment to the United States.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

Monthly establishments are conducted, and appropriate corrective actions were initiated by the inspection service.

Enforcement Activities

Latest FSIS Quarterly Regulation and Enforcement Report (January – March 2000) was presented to EELA officials. It was stated that enforcement action pertaining to fine, product confiscation, and imprisonment was not published in Finland.

EELA inspectors conduct continuous inspection in combination slaughter-processing establishments, and the Municipal (official) veterinary officers in the respective provinces perform monthly in-depth reviews of the U.S.-certified establishments. The audit results are provided to the establishment and to the EELA in Helsinki. In case of violation of the requirements or noncompliance by the establishments, according to §§ 28 and 38 of the Act and the stipulations therein and provisions based on it, the Municipal veterinary authority must issue a warning for health considerations a notice to the establishments to seek compliance, and take appropriate actions to prevent public health hazard. If the requested noncompliance is not

rectified then they temporarily revoke in full or partially the registration or suspend operations for a given period, and/or revoke the registration of the establishments, and inform EELA.

The laws (§§ 29 to 31, and §§ 33 to 37) imply that the inspection service can prevent distribution of unsuitable product in the market. Such product can be destroyed (§ 48). The violators may also be imposed punitive fines or imprisonment of six months. Similar actions can be taken under if inspectors are threatened or intimidated (as described in § 32) in the discharge of these acts, the penalty is up to six months imprisonment (§ 46).

For example: EELA revoked the registration (closed) of a poultry establishment on October 2, 2000 for continued noncompliance and endangering public health. In another instance, recently, in a cold store, EELA inspectors found unmarked (un-inspected) product that originated in an official small poultry establishment. On further investigation, it was found such un-inspected product had also been distributed along with a large inspected consignment by the establishment directly. EELA recalled and confiscated all product shipped out of the cold store, and took the poultry establishment to the court of law where it was fined. However, the establishment has appealed to higher court against the fine judgement.

The official EELA's case report was available and reviewed by the auditor; however, these reports are not published.

Exit Meeting

An exit meeting was conducted in Helsinki on October 3, 2000, and was attended by Dr. Osmo Mäki-Petäys, Head Department of Food Control/EELA, Dr. Anna-Maija Grönlund, Senior Veterinary Officer/EELA, Dr. Tiina Laitala, Senior Veterinary Officer/EELA, Eija-Riitta Venalainen, National Research Institute Laboratory, Dr. Ulla Perttila, National Research Institute Laboratory, and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS, Field Operations. Observations made during the audit and stated above were discussed. Dr. Dr. Osmo Mäki-Petäys stated that:

1. All inspectors would be trained in PR/HACCP twice annually.
2. Guidelines have been developed for the inspectors and the establishments on procedures of sanitary handling of incidentally dropped meats.
3. EELA would look into possible ways of denaturing of DOA carcasses, condemned and inedible product.
4. The establishments have been asked to use process control techniques (charting or plotting results overtime) for generic *E. coli* to determine variations in test results, and guidelines are being developed on how to establish normal limits for process control.
5. Each lot of product would be tested for species identification before shipment to the United States.

Ms Vanalainen stated that arsenic and mercury would be included in CY 2001 plan. Dr. Pertilla stated that the procedures used for sample analyses turn-round time, target matrices for sampling, recoveries percentages, and laboratory check samples were consistent with national, and EU

recommended Laboratory Quality Control requirements and comparable with international standards.

CONCLUSION

The inspection system was found to have effective controls in place in all the establishments, and ensured that the product destined for export to the United States was produced under conditions equivalent to those that FSIS requires in domestic establishments.

Hussain Magsi, DVM, MS
International Audit Staff Officer

Signed) *Hussain Magsi, DVM, MS*

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible individual Identified	7. Docu-mentation done daily	8. Dated and signed
10	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√
64	√	√	√	√	√	√	√	√
74	√	√	√	√	√	√	√	√
48	√	√	√	√	√	√	√	√
6472	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
1. The HACCP plan was validated using multiple monitoring results.
2. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1. Flow diagram	2. Hazard analysis done	3. All hazards ident-ified	4. Use & users includ-ed	5. Plan for each hazard	6. CCPs for all hazards	7. Monitor-ing specifie d	8. Correac-tive actions described	9. Plan valida-ted	10. Adequate verific. Proced-ures	11. Adequat e docu-menta-tion	12. Dated and signed
10	√	√	√	√	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√	√	√
74	√	√	√	√	√	√	√	√	√	√	√	√
78	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data collection instruments for *E. coli* testing

Following information was collected.

1. The establishment has a written procedure for testing for generic *Enterobacteriaceae.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. No.	1.Writ-ten procedure	2. Sample collector designa-ted	3.Samp-ling location given	4.Predomi-nant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
10	√	√	√	√	√	√	√	√	*No	√
18	√	√	√	√	√	√	√	√	*No	√
22	√	√	√	√	√	√	√	√	*No	√
62	√	√	√	√	√	√	√	√	*No	√
74	√	√	√	√	√	√	√	√	*No	√
78	√	√	√	√	√	√	√	√	*No	√

* Statistical process control limits were not established, and graphing/charting for results was not done.

Attachment D

Data Collection instruments for *Salmonella* spp. Testing

Establishment 80 was evaluated to determine if the *Salmonella* species performance standards requirement met U.S. requirement criteria approved for equivalence.

The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

* Est. Number	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est stop operations
10	√	√	√	√	√	√
18	√	√	√	√	√	√
22	√	√	√	√	√	√
62	√	√	√	√	√	√
74	√	√	√	√	√	√
78	√	√	√	√	√	√