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AUDIT REPORT FOR DENMARK
MARCH 14 THROUGH APRIL 10, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Denmark's meat inspection system from March 14 through April 10, 2001. Nine of the 99 establishments certified to export meat to the United States were audited. Six of these were slaughter and processing establishments; two were conducting processing operations, and the remaining establishment was a cold storage facility.

The last audit of the Danish meat inspection system was conducted in September 2000. Nine were audited: seven (Ests. 15, 53, 79, 220, 319, 337, and 469) were acceptable and two (Ests. 28 and 47) were evaluated as acceptable/re-review. The deficiencies reported at that time included inadequacies regarding post-mortem inspection procedures, inadequate documentation of Sanitation Standard Operating Procedures, lack of monthly internal reviews of establishments, non-implementation of the requirement for pre-shipment document reviews, and inadequate light intensity at post-mortem inspection stations.

Beef products were ineligible for export to the U.S. at the time of this audit, due to the presence of Bovine Spongiform Encephalopathy in Europe, and because of the outbreak of Foot and Mouth Disease in Europe shortly before this audit began. Only canned pork products were being accepted from Denmark at U.S. ports of entry.

During the period from January 1 to February 28, 2001, Danish establishments exported 21,195,742 lbs. of pork and pork products to the U.S. Of these products, 7,125,384 lbs. were reinspected at U.S. ports of entry; a total of 98,835 lbs. (slightly less than 1.4%) of the reinspected products were rejected for processing defects (1% of the amount reinspected), pathology (0.24%), transportation damage (0.07%), and missing shipping marks (0.05%). During calendar year 2000, Danish establishments exported 137,170,224 lbs. of pork and pork products to the U.S. Of these products, 39,359,270 lbs. were reinspected at U.S. ports of entry; a total of 387,097 lbs. (slightly less than 1%) of the reinspected products were rejected were for labeling defects (0.25% of the amount reinspected), violative net weight (0.22%), transportation damage (0.14%), processing defects (0.1%), unsound condition (0.09%), missing shipping marks (0.08%), contamination (0.07%), and pathology (0.04%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Danish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the several of the Danish

Veterinary and Food Administration's regional headquarters offices. The third was conducted by on-site visits to establishments. (The two establishments that had been evaluated as acceptable/re-review during the previous audit were visited again; the remainder of the establishments selected for on-site audits and those selected for document audits were chosen randomly.) The fourth part involved visits to four laboratories, one performing analytical testing of field samples for the national residue testing program, and three others culturing field samples for the presence of microbiological contamination with *Salmonella* species and *Escherichia coli (E. coli)*. One of the latter three was a government laboratory; the other two were private.

Denmark's program effectiveness was assessed by evaluating 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 and operation 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.

During all 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 (none of the establishments audited at this time were unacceptable).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all nine of the establishments audited; two of these (Ests. 71 and 190) were recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report.

As stated above, among the concerns that had been identified during the last audit of the Danish meat inspection system, conducted in September-October 2000, were the following:

1. Inadequacies regarding post-mortem inspection procedures. *The post-mortem inspection procedures were now found to be complete and professionally conducted in all of the six slaughter establishments audited.*

2. Inadequate documentation of Sanitation Standard Operating Procedures in two establishments. *Inadequate documentation was again found in two establishments.*

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3. Lack of monthly internal reviews in six establishments. *Considerable improvement in the monthly internal review program had been made.*

4. Non-implementation of the requirement for pre-shipment document reviews. *Pre-shipment document reviews had been implemented in all but one of the establishments visited on-site by the dates of the individual audits.*

5. Inadequate light intensity at post-mortem inspection stations in four of the six slaughter plants visited. *Light was adequate in all slaughter establishments except in the retained carcass inspection areas in two establishments.*

Entrance Meeting

On January 20, an entrance meeting was held in the Mørkhøj offices of the *Danish Veterinary and Food Administration (DVFA)*, and was attended by Dr. Kristian Hermannsen, Asst. Chief Veterinary Officer and head of the Unit for Export Equivalence and Certification; Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Dr. Justin Ajufo, Veterinary Officer, Division for Food Safety; Dr. Mette Hjulmand-Lassen, Veterinary Officer, Division for Food Safety; Mr. Finn Haunstrup Clemmensen, Head of the Division for Control Coordination; Dr. Mette Espersen, Veterinary Officer, Institute for Food Safety and Toxicology; Mr. Flemming Kærby, M.Sc, Institute for Food Research and Nutrition; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. There were changes in the organizational structure. A new organizational chart was presented at the exit meeting.

2. Foot-and-Mouth Disease (FMD) had been confirmed in France the day before this entrance meeting with the Danish officials; the Danes stated that the measures being taken to keep Denmark free of FMD were being published on their Website, at: http://www.fdir.dk; link FMD.

3. Details of the itinerary were discussed and finalized.

Headquarters Audit

There had been a few changes in the organizational structure since the last U.S. audit of Denmark's inspection system in September 2000. A new organizational chart was provided.

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

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The auditor conducted audits of inspection system documents pertaining to the establishments listed for records review. These records audits were conducted at the regional office. The records review focused primarily on food safety hazards and included the following:

- Monthly internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing, and *Salmonella* testing.
- Export product inspection and control.

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

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Denmark as eligible to export meat products to the United States were full-time DVFA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Ninety-nine establishments were certified to export meat products to the United States at the time this audit was conducted. Nine establishments were visited for on-site audits. In all of the establishments visited, except as noted below, both DVFA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Fødevareregion Aarhus Laboratory in Aarhus was audited on March 23, 2001. Effective controls were in place for sample handling, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

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The check sample program was designed to fulfill European Commission requirements. Intra-laboratory check samples were not being performed in this laboratory. International check samples were provided by FAPAS in England and had been performed in April and October 2000 for organochlorines and were scheduled for June and October 2001; the schedule also called for two check samples each for trace elements for April, July, and November 2001.

A new method for organochlorine pesticides and PCBs had just recently been developed, and the sampling requests had just been distributed at the end of February. Note: all the planned analyses for CY 2000 had been completed.

The sampling for trace elements was just getting underway. Previously two other laboratories were also performing the analyses for these; this laboratory will now undertake the entire country's testing for trace elements. Note: Arsenic was not part of the sampling plan at the moment; new equipment was acquired five months previously and optimization was still ongoing. Current sampling was for lead, mercury, cadmium, and selenium.

The quality control system did not include the documentation of the preparation of fresh standard solutions in a bound notebook with previously numbered pages. The laboratory officials agreed to correct this.

Denmark's microbiological testing for *Salmonella* was being performed in both private and government laboratories. One government laboratory (the Laboratory of Fødevareregion Sønderjylland, in Haderslev) and two private laboratories, situated in the Danish Crown slaughter establishments in Horsens and Saeby, were audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

<u>Establishment Operations by Establishment Number</u>

The following operations were being conducted in the nine establishments:

Cold storage – Est. 165
Swine slaughter and pork cutting – Est. 91
Pork cutting, boning, and packaging – Est. 339

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Swine slaughter, cutting, and curing – Est. 28
Beef and pork cutting and cold storage – Est. 190
Swine slaughter, cutting, boning, and curing – Est. 71
Swine slaughter, boning, cutting, curing, sausages, and hams (retort pouch, not-shelf stable) – Est. 25
Swine slaughter, cutting, boning, cooked and uncooked pork loin back ribs, spareribs, and cooked bones – Est. 38
Swine and beef slaughter; pork and beef cutting and cooked sausage production and occasional curing of ham and pork backs – Est. 47

SANITATION CONTROLS

Based on the on-site audits of establishments, Denmark's inspection system had controls in place for water potability; chlorination procedures; back-siphonage prevention; temperature; operations and inspectors' work space; ventilation; over-product ceilings and equipment; dry storage areas; ante-mortem facilities; welfare facilities; outside premises; personal dress, habits, and hygiene procedures; product transportation; maintenance; and waste disposal.

Sanitation Standard 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).

The SSOPs in the establishments visited were found to meet the basic FSIS regulatory requirements, with the exception of documentation in four of them.

In Est. 25, heavy, dripping condensation was observed directly over exposed carcasses in numerous areas in the coolers during the audit. A review of the establishment's documentation revealed no mention of any condensation problems or corrective actions. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately monthly: No condensation problems had been noted during January or February 2001.

In Est. 71, heavy, dripping condensation was observed directly over clean containers ready for use in one large boning area. A review of the establishment's documentation revealed no mention of any operational condensation problems or corrective actions since February 1, 2001. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately weekly; lack of the establishment's documentation of condensation problems had been noted.

In Ests. 91 and 190, there was documentation of sanitation activities, but it was in need of improvement.

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The importance of documentation of pre-operational and operational sanitation activities, findings, and corrective actions was stressed both in the meetings in the individual establishments and during the exit meeting with Danish officials. Assurances were given that improvements would be implemented promptly.

The following sanitation deficiencies were also identified:

Product Handling and Storage

1. In Est. 25, exposed product was stored directly below heavy, dripping condensation on cooling units in several areas of the (extensive) carcass coolers. DVFA officials ordered complete reinspection and trimming, as necessary, of all affected product, development of a program for improved monitoring and documentation of condensation control, and rejected the affected rails pending elimination of the cause.

2. In Est. 71, a stack of edible containers, ready for use, was stored under an area of heavy condensation on the ceiling in the corner of one large cutting room. The establishment sent the containers for re-cleaning, but later in the review another piece of equipment used for transporting edible containers was found to be stored in the same location. The area was rejected for personnel- and product-contact equipment traffic.

3. In Est. 190, exposed product was stored directly underneath rusty overhead structures in a cooler. Cleaning and painting were scheduled and measures were put in place to prevent storage of product under the area in question.

Cross-Contamination

1. In Est. 38, several swine carcass heads were observed contacting an inedible container at the station where stick wounds were trimmed. Corrective action by management was immediate.

2. In Est. 91, a floor-cleaning employee contaminated two edible product containers and two hams. The Veterinarian-In-Charge ordered cleaning of the edible product containers and trimming of the contaminated product.

Sanitizers

1. Sanitizing facilities for the splitting saws used at the retained inspection area in Est. 91 were inadequate. The DVFA official ordered prompt installation of an adequate sanitizer. Three sanitizers on the slaughter floor, at trim stations after the post-mortem inspection, were below the required temperatures. The establishment General Director took immediate corrective action.

2. In Est. 71, there was no sanitizer in the pre-boning trim area. The DVFA officials ordered immediate correction.

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Personnel Hygiene and Practices

1. An edible-product worker in Est. 38 failed to wash his hands and change his gloves after contaminating them through contact with a piece of meat that had fallen onto the floor. The management official ensured that he washed his hands and changed gloves.

2. An edible-product worker in Est. 71 was observed to contaminate his hands on an inedible container and not wash his hands before returning to work. The DVFA officials took immediate corrective action.

3. Three workers in the boning room in Est. 190 did not wash their hands when returning from a break. Another worker hung his apron on a wall hook intended for storage of, and in contact with, a shovel used for meat that had fallen on the floor. The establishment official took immediate corrective actions.

4. Several workers in Est. 339 were observed to contaminate their aprons through contact with an inedible container in the receiving area. DVFA officials took immediate corrective actions.

Product-Contact Equipment

1. Several stainless steel combo bins in Est. 28 had cracked and torn corners. These were retained by the Veterinarian-In-Charge for repair or replacement.

2. Inadequately cleaned plastic containers were ready for use in one production area of Est. 91. Corrective action was taken immediately by the inspection personnel.

3. An obvious grease spot on a cutting board was ignored by a worker returning from a break in Est. 190. DVFA officials ordered immediate cleaning and disinfection.

Over-Product Equipment

1. Maintenance of over-product structures had been neglected in a few areas in Est. 25: Mold was observed on the edges of skylights, mold and old product residues on hoist controls, and old product residues on rail gate switch handles. Management officials agreed to conduct a thorough inspection and take corrective actions as necessary.

2. In Est. 38, old product residues were found on rail gates in the main cutting room. The management officials initiated immediate corrective actions, and DVFA officials ordered increased maintenance and pre-operational monitoring.

3. Heavy rust, flaking paint, and heavy, dried and flaking grease were observed on over-product equipment in the pre-boning trim area in Est. 71. Management officials agreed to clean the area promptly.

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4. Rust was present in Est. 190 on overhead structures in a cooler, with exposed product stored directly underneath. Cleaning and painting were scheduled and measures were put in place to prevent storage of product under the area in question.

Dry Storage Areas

1. Heavy dust buildup was found on many sacks and other containers of non-meat ingredients in the dry storage area in Est. 25; also, detritus and live spiders were present in inaccessible spaces between racks and walls. DVFA officials ordered (1) a prompt, thorough cleaning regimen, to begin before the next day's production, (2) inspection by processing personnel of all non-meat ingredients from the area before use in production, and (3) development of a reliable cleaning and maintenance program, including moving racks to enable cleaning behind them.

2. Dead insects and spider webs were in evidence on slanting windowsills above stored packaging materials. The management official ordered the room to be thoroughly cleaned before the next day's production.

Other Sanitation Deficiencies in Individual Establishments

1. The dropped-meat reconditioning procedure in Est. 190, as demonstrated, was unacceptable, resulting in gross contamination of the meat to be trimmed and of the work surface on which the procedure was performed. The knife was not sanitized after being contaminated. The DVFA internal reviewer who was leading the audit stopped the procedure, condemned the meat, and ordered termination of dropped-meat reconditioning until such time as the establishment could demonstrate to DVFA the capability of performing the procedure in a sanitary manner.

2. There were no hand-washing facilities in one production area in Est. 25. DVFA officials ordered prompt correction.

3. In Est. 28, several doors between production areas and outside premises were left open during operations. Corrective actions by the establishment management officials were immediate, and the Veterinarian-In-Charge ordered implementation of an improved policy.

ANIMAL DISEASE CONTROLS

Denmark’s inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned product. There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

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During the months preceding this audit, Foot-and Mouth Disease had broken out in England, Northern Ireland, the Republic of Ireland, the Netherlands, and France. The Danish officials had devoted considerable effort to keeping Denmark free of the disease. An up-to-date report on the status of these controls is available through the Website: http://www.fdir.dk; link FMD.

RESIDUE CONTROLS

Denmark's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Danish inspection system had adequate controls in place to ensure compliance with residue sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Danish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredients identification, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment and records, empty can inspection filling procedures, container closure exam, interim and post-processing handling, incubation procedures, processing defect actions by establishment personnel, and processing control by inspection personnel..

HACCP Implementation

All establishments approved to export meat products to the U.S. are 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 used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

1. In all but one (Est. 190) of the establishments audited on-site, pre-shipment document reviews had been developed and implemented by the time of the individual audits. Of the sixteen establishments selected for document reviews, no pre-shipment document reviews had as yet been developed and implemented in nine (Ests. 29, 30, 31, 53, 65, 95, 211, 260, and 417). Considerable work had gone into the fulfillment of this requirement since the previous FSIS audit, and the DVFA officials gave assurances that it would be universally in place in all establishments certified to produce products eligible for export to the United States within a very short time.

2. There was a Critical Control Point in Est. 71 for cooler temperatures. A review of the documentation revealed that there was consistent documentation for the temperatures, but documentation of corrective actions when critical limits were exceeded was inadequate.

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3. No procedures to verify that the HACCP plan was being effectively implemented and functioning as designed had been developed and implemented in Est. 190. The FSIS auditor discussed the requirement both in the establishment and during the exit meeting in Copenhagen, and the DVFA officials gave assurances the requirement would be promptly met.

Testing for Generic *E. coli*

Six of the establishments audited on-site and five of those selected for document review were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Denmark had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following different equivalent requirements:

1. SAMPLING TOOLS

- Denmark was using a gauze swab sampling tool. The gauze swab is a generally/ internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.

- The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.

- The sampling tool does not contaminate the surfaces of the carcass.

2. ANALYTICAL METHODS: different methods.

- Denmark was using an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.

- The method is approved by the AOAC International or an internationally recognized scientific organization.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Danish domestic consumption from being commingled with products eligible for export to the United States.

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ENFORCEMENT CONTROLS

Inspection System Controls

The DVFA inspection system controls [animal identification, ante-and post-mortem inspection dispositions, control of restricted product and inspection samples, condemned and restricted product control, control of restricted product and inspection samples, boneless meat reinspection, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans—see the exception noted above for Est. 71), inspection supervision and documentation,] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

No meat imported from other countries, or meat from live animals imported from other countries, was used in any product eligible for export to the United States.

Testing for *Salmonella* Species

Six of the establishments audited on-site and five of those selected for document review were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Denmark had adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

1. SAMPLE COLLECTOR: establishments take samples.

   - The government of Denmark provides a clearly written sampling plan with instructions for sample collection and processing that is followed by all applicable export establishments.

   - All applicable veterinarians are properly and uniformly trained; they train the establishment employees. The trained veterinarian observes the collection/storage/transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and DVFA analyzes the sample.

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- The government of Denmark uses the test results to monitor establishment performance over time.

- The government of Denmark takes immediate action any time an establishment fails to meet *Salmonella* performance standards.

2. LABORATORIES: private laboratories analyze samples.

   - The laboratories are independent non-government or establishment laboratories that are accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyses are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.

   - All accredited laboratories have a formal program to ensure that lab personnel are properly trained, there are suitable facilities and equipment, there is a written quality assurance program, and there are adequate reporting and record keeping facilities.

   - Test results are provided directly to the government veterinarian.

3. SALMONELLA TESTING STRATEGY.

   - Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.

   - Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.

   - Denmark's testing program has statistical criteria for evaluating test results.

   - The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

4. SAMPLING TOOLS.

   - The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.

   - The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.

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- The sampling tool does not contaminate the surfaces of the carcass.

Furthermore, the official veterinarian in each slaughter establishment takes an independent sample once weekly for *Salmonella* analysis. These official samples serve as verification of those taken by the establishments, and are analyzed at an official laboratory.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, Denmark was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements.

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 frequently 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.

The systems in place for the completion of, and the responsibility for, the monthly reviews was found to vary considerably between the meat inspection regions:

In the region of ***Ringsted***, which had five establishments listed for U.S.-export, the monthly internal reviews were being conducted by the Veterinarians-In-Charge at other U.S.-listed establishments in the region. The Head of the regional office of the Food Inspection Service in Ringsted designated which veterinarians were to have this responsibility. These internal auditors submitted copies of their reports to the regional offices for review.

In the region of ***Fyn***, there was a designated individual who performed the monthly reviews of the five establishments certified for U.S. export (29, 45, 175, 187, and 198).

In the region of ***Sønderjylland,*** no one had been specifically assigned the duty of performing the monthly supervisory reviews during the first four months of 2000. As of May 2000, the Chief Veterinarians in the two slaughterhouses in the region had the responsi-bility to conduct the monthly reviews in the region, and were assigned this duty by the head of the regional office of DVFA.

In the region of ***Esbjerg,*** before January 1, 2001, the Veterinarians-In-Charge at the two U.S.-certified slaughter plants (Ests. 53 and 340) conducted the monthly internal reviews of each other's assigned establishments, and the inspectors assigned to the other four plants were conducting the monthly reviews of the establishments to which they were assigned, assisted, on occasion, by officials from the regional office. Since January 1, 2001, the Veterinarians-In-Charge at Ests. 53 and 340 have continued to conduct the

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monthly internal reviews of each others' assigned establishments, and two officials from the regional office now participate in these duties: One of them and one of the Veterinarians-In-Charge at either Ests. 53 or Est. 340, as a team of two, had conducted the monthly internal reviews of the other four plants certified for US-export.

In the region of ***Aarhus,*** as of January 1, 2001, one veterinarian from the regional office had had the assignment of performing the internal reviews of the establishment certified to export to the U.S. He had been assisted in some of these internal reviews by the Veterinarian-In-Charge of Establishment 220 in Brabrand and also by two other veterinarians from the regional office.

In the region of ***Vejle,*** there were 11 establishments listed for U.S. export. Four of the Veterinarians-In-Charge participated in the monthly internal review process, conducting the reviews of establishments other than those in which they were stationed, and the reviews of any given establishment were performed, in different months, by different reviewers. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Vejle. He evaluated the contents of the reports and discussed the findings with the reviewing officers.

In the region of ***Herning,*** the internal reviews of the eight establishments certified for U.S. export were conducted by six Veterinarians-In-Charge of these establishments. An internal review of an establishment was never conducted by the Veterinarian-In-Charge of that establishment. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Herning. She reviewed the contents of the reports and discussed the findings with the reviewing officers. Starting April 1, 2001, two veterinarians employed in the regional office in Herning will assume the responsibility for the monthly internal reviews; the Veterinarians-In-Charge who were doing this at the time of this audit will then continue to review, on a quarterly basis, the quality control systems in plants other than those in which they are stationed.

In the region of ***Viborg,*** the monthly internal reviews of the eleven establishments certified for U.S. export were conducted by four Veterinarians-In-Charge and one Deputy Veterinarian-In-Charge of three of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Herning. She reviewed the contents of the reports and discussed the findings with the reviewing officers.

In the region of ***Nordjylland,*** under the system in place at the time of the audit, the monthly internal reviews of the four slaughter establishments certified for U.S. export (Ests. 13, 28, 62, and 71) were being conducted by the Veterinarians-In-Charge of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The Veterinarians-In-Charge of the other eleven (non-slaughter) establishments certified for U.S. export were conducting the internal reviews of the establishments in which they were stationed. Note: only three of these (211, 337, and

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469) had exported any products to the U.S. during CY 2000. Starting on May 1, 2001, the VIC in each of the four slaughter establishments was to assume responsibility for supervision of the activities in several of the eleven smaller plants; however, the internal reviews of each of these smaller plants was to be conducted by the Veterinarian-In-Charge who supervised a different set of small plants.

The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the offices of the Regional Authorities.

During the period since the previous FSIS audit, internal reviews were conducted each month at eighteen of the establishments audited. The Auditor examined the internal review reports for the establishments selected both for on-site audits and for document audits, and determined that the supervisory visits had been missed for one month in five establishments and for two months in two establishments. (This represented a considerable improvement in the internal reviews compared to the previous FSIS audit, during which it had been determined that internal reviews were conducted each month at only three of the twenty establishments audited.) The requirement that the internal reviews are to be performed each month when U.S.-eligible production is conducted was emphasized during the meetings with inspection personnel both in the field and in the exit meeting in Copenhagen. The DVFA officials gave assurances that they were aware of the requirement and would ensure that they would be conducted on a monthly basis, at a minimum.

Enforcement Activities

The Danish Veterinary and Food Administration publishes an extensive summary of the Agency's enforcement activities in the form of a compliance report on their Website. This report is very similar in scope and content to the Quarterly Enforcement Report published on FSIS's Website.

Exit Meetings

An exit meeting was conducted in Copenhagen on April 10. The Danish participants were Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Mr. Flemming Kærby, M.Sc, institute for Food Research and Nutrition; Ms. Susann Jensen, Food Scientist, Division of Food Safety; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The findings encountered in the course of the audits were discussed and the DVFA officials gave assurances that:

1. Improvements would be implemented promptly in those establishments in which the documentation of pre-operational and operational sanitation activities, findings, and corrective actions had been found deficient.

2. Implementation of pre-shipment document reviews would be mandated in the remaining establishments certified as eligible to produce U.S.-eligible products.

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3. Increased attention would be devoted to the monitoring of condensation controls in Establishments 25 and 71.

4. The installation of the necessary sanitizers in Ests. 1 and 91 would be ensured.

5. Effective improvements in the maintenance and cleaning of over-product equipment would be implemented in Ests. 25, 38, 71, and 190.

6. Documented internal reviews of all establishments would be conducted during all months in which production of U.S.–eligible product takes place.

CONCLUSION

The inspection system of Denmark was found to have effective controls in place, or adequate corrective actions were taken, to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Nine establishments were audited on-site: seven were acceptable and two were evaluated as acceptable/re-review. All deficiencies encountered during the on-site establishment audits were adequately addressed to the Auditor's satisfaction

Dr. Gary D. Bolstad (signed) Dr. Gary Bolstad
International Audit Staff Officer

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
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)

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Attachment A-1

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 documentation audited from the following establishments that were visited on-site were as follows:

	1	2	3	4	5	6	7	8
25	√	√	√	√	√	√	Inadeq.	√
28	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	Inadeq.	√
91	√	√	√	√	√	√	√*	√
165	√	√	√	√	√	√	√	√
190	√	√	√	√	√	√	√*	√
339	√	√	√	√	√	√	√	√

25 -- Heavy, dripping condensation was observed directly over exposed carcasses in numerous areas in the coolers during the audit. A review of the establishment's documentation revealed no mention of any condensation problems or corrective actions. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately monthly: No condensation problems had been noted during January or February 2001.

71 -- Heavy, dripping condensation was observed directly over clean containers ready for use in one large boning area. A review of the establishment's documentation revealed no mention of any operational condensation problems or corrective actions since February 1, 2001. The in-plant inspection service personnel were verifying the establishment's docu-mentation of SSOPs approximately weekly; lack of the establishment's documentation of condensation problems had been noted.

91, 190 – There was documentation, but it was in need of improvement.

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Documentation was also audited from the following establishments that were not visited on-site:

	1	2	3	4	5	6	7	8
29	√	√	√	√	√	√	√*	√
30	√	√	√	√	√	√	√*	√
31	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√*	√
65	√	√	√	√	√	√	√*	√
85	√	√	√	√	√	√	√	√
95	√	√	√	√	√	√	√	√
161	√	√	√	N/A*	√	√	√	√
177	√	√	√	N/A*	√	√	√*	√
178	√	√	√	√	√	√	√*	√
188	√	√	√	√	√	√	√	√
211	√	√	√	√	√	√	√	√
260	√	√	√	√	√	√	√	√
337	√	√	√	√	√	√	√	√
340	√	√	√	√	√	√	√*	√
417	√	√	√	√	√	√	√*	√

Column 7: The DVFA inspection officials gave assurrances that the establishments' documentation was performed as required.

65 Establishment documentation of sanitation had improved, according to the inspection personnel; but documentation of DVFA monitoring of the establishment's fulfilling of its responsibilities, meeting target dates, etc. was in need of improvement.

161 This was strictly a cold storage facility

177 This was strictly a cold-store facility. There were no product-contact surfaces.

Attachment B-1

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 has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. 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.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. 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.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
25	√	√	√	√	√	√	√	√	√	√	√	√*
28	√	√	√	√	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√	√	√	√	√*
47	√	√	√	√	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	√	√	√	Inad.	√	√
91	√	√	√	√	√	√	√	√	√	√	√	N/A*
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	√	√	√	√	√	√	√*	√	no	√	√	no
339	√	√	√	√	√	√	√	√	√	√	√	√

25 – Pre-shipment document reviews were being conducted, but only since 3/12/01 (3 days prior to this audit).
38 – Pre-shipment document reviews were being conducted, but only since 3/28/01 (1 day prior to this audit).
71—There was documentation for the temperatures in the coolers, but documentation of corrective actions when critical limits were exceeded was inadequate.
91 – Product from Est. 91 was not yet U.S.-eligible. A Pre-Shipment Document Review form was being developed.
190 – There was some documentation, but improvement was needed.

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Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users include-ed	4. Plan for each product	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. Proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
29	√	√	√	√	√	√	√	√	√	√	√	no*
30	√	√	√	√	√	√	√	√	√	√*	√	no
31	√	√	√	√	√	√	√	√	√	√	√	no*
53	√	√	√	√	√	√	√	√	√	√	√	no
65	√	√	√	√	√	√	√	√	√	√*	√	no
85	√	√	√	√	√	√	√	√	√	√	√	√
95	√	√	√	√	√	√	√	√	√	√	√	no*
161	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	√	√	√	√	√	√	√	√	√	√*	√	no
260	√	√	√	√	√	√	√	√	√	√	√	no
337	√	√	√	√	√	√	√	√	√	√	√	√
340	√	√	√	√	√	√	√	√	√	√	√	√*
417	√	√	√	√	√	√	√	√	√	√	√	no*

29, 31, 95—A document for Pre-Shipment Document Reviews had been developed by Danish Crown and provided to the Veterinarian-In-Charge for comments and was available in the documents provided for audit, but its use had not yet been implemented.

30 —The Vet-In-Charge reported that the establishment tended to be lax in documentation of corrective actions, but that he had taken steps to assure improvement.

211— The Vet-In-Charge had identified that the establishment tended to be lax in documentation of the monitoring of some critical limits, but she had taken steps to assure improvement.

65—Establishment documentation was adequate, but there was practically no documentation of inspection oversight of the establishment's fulfilling of its HACCP requirements.

340—Pre-Shipment Document Reviews were implemented 3/15/01.

417—This was strictly a casings operation.

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Data Collection Instrument for Generic *E. coli* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing 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 procedure for testing for generic *E. coli.*
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/are 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.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. 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
25	√	√	√	√	√	√	√	√	√	√
28	√	√	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	√	√	√	√
91	√	√	√	√	√	√	√	√	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
339	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. 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
29	√	√	√	√	√	√	√	√	√	√
30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
31	√	√	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√	√	√
65	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
95	√	√	√	√	√	√	√	√	√	√
161	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
337	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
340	√	√	√	√	√	√	√	√	√	√
417	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

31 *The rails were chosen at random; carcasses at the ends of the rails were sampled. The other half of the same carcass was used for Salmonella testing.*

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Attachment D-1

Data Collection Instrument for *Salmonella* testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. 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) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	*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's stop operations
25	√	√	N/A	√	√	N/A
28	√	√	N/A	√	√	N/A
38	√	√	N/A	√	√	N/A
47	√	√	N/A	√	√	N/A
71	√	√	N/A	√	√	N/A
91	√	√	N/A	√	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A
339	N/A	N/A	N/A	N/A	N/A	N/A

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Documentation was also audited from the following establishments that were not visited on-site.

Est. #	*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's stop operations
29	√	√	N/A	√	√	N/A
30	√	N/A	√	√	√	N/A
31	√	√	N/A	√	√	N/A
53	√	√	N/A	√	√	N/A
65	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A
95	√	√	N/A	√	√	N/A
161	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A
260	√	N/A	√	√	√	N/A
337	N/A	N/A	N/A	N/A	N/A	N/A
340	√	√	N/A	√	√	N/A
417	N/A	N/A	N/A	N/A	N/A	N/A