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

Henning Petersen
Veterinary Officer
Danish Veterinary and Food Administration
International Trade Division
Mørkhøj Bygade 19
DK–2860 Søborg
Denmark

SEP 17 2007

Dear Dr. Petersen:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Denmark's meat inspection system May 1 to June 6, 2007. Comments from Denmark have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

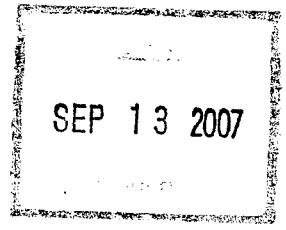
Sincerely,

Donald C. Smart

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL



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

APRIL 17 THROUGH MAY 11, 2007

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

MFCA	Ministry of Family and Consumer Affairs
CCA	Central Competent Authority (Danish Veterinary and Food Administration)
CCP	Critical Control Point
CL	Critical Limit
DVFA	Danish Veterinary and Food Administration
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RVFAC	Regional Veterinary and Food Administration Centre
RVS	Regional Veterinary Supervisor for the U.S. certified establishments
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Denmark from April 17 through May 11, 2007.

An opening meeting was held on April 17, 2007, in Mørkhøj (Copenhagen) with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Denmark's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the International Trade Division (ITD), Audit Unit, a division within the Danish Veterinary and Food Administration (DVFA).

2. OBJECTIVE OF THE AUDIT

This audit was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one regional inspection office, six swine slaughter and meat processing establishments, one meat processing establishment, one cold storage facility, one laboratory conducting microbiological testing on United States-destined product, and one laboratory performing analytical testing for the National Residue Testing Program.

Competent Authority Visit			Comments
	Central	1	
	Regional	1	
	Local	8	Establishment level
Laboratories		2	
Slaughter and Meat Processing Establishments		6	
Meat Processing Establishment		1	
Cold Storage Facility		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to eight establishments: six swine slaughter and meat processing establishments, one meat processing establishment and one cold storage facility. The fourth part involved visits to two government laboratories. The Regional Veterinary and Food Administration Centre (RVFAC) laboratories that conduct microbiology samples for *Salmonella* testing as well as residue analytical testing of field samples for the national residue testing program, located in Ringsted, was audited.

Program effectiveness determinations of Denmark's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Denmark's inspection system was assessed by evaluating these five risk areas.

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

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

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Denmark under provisions of the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement. Currently, Denmark has the same requirement for generic *E. coli* testing as FSIS with the following exceptions:

- A gauze pad sampling tool is used
- NMKL or AOAC 991.14 method is used to analyze samples.
- Use of *Enterobacteriaceae* and Total Viable Count in Lieu of Generic *E. coli* Testing.

Denmark has the same requirement as FSIS for Salmonella testing for pathogen reduction performance standards with the following exceptions:

- The establishments take the samples.
- Private laboratories analyze the samples.
- Continuous, on-going sampling program is used.
- A gauze pad sampling tool is used.
- NMKL method # 71and IQ Check method are used to analyze samples.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat.
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products.
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The last two FSIS audits of Denmark's meat inspection system were conducted in September 2004 and June through August 2005. There was no audit in 2006:

All audit findings identified during the January/February 2003 audit were found to have been corrected during the September 2004 audit except for the following:

- Preventive measures for corrective actions were not included in the daily SSOP records.
- Noncompliances were not sufficiently documented.
- Ongoing verification activities for the direct observation of monitoring of critical limits and corrective actions were not performed.
- Ongoing verification activities for the review of records generated and maintained were not performed.
- The establishment did not include in their HACCP plan corrective actions identifying the cause and elimination of a deviation and did not establish measures to prevent recurrence when a deviation from a critical limit was identified.

The following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted in September, 2004:

- One establishment did not monitor daily the implementation of the procedures in the SSOP.
- Six establishments were not maintaining daily records sufficient to document the implementation and monitoring of the establishment's SSOP.
- Seven establishments did not meet the requirements of EC Directive 64/433 and were not operating and maintained in a manner sufficient to prevent creation of insanitary conditions and to ensure that product is not adulterated.
- Nine establishments failed to implement their HACCP plans.
- One establishment did not meet FSIS requirements for the production of ready-to-eat products for export to the United States.
- In one establishment, the DVFA did not provide direct and continuous official supervision of preparation of product by the assignment of inspectors to the second and third shifts to assure that adulterated or misbranded product is not prepared for export to the United States.
- FSIS requirements were not enforced in nine establishments.

The following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted June 29 through August 4, 2005:

- Four establishments did not monitor daily the implementation of the procedures in the SSOP. For example:

    - An establishment employee, eviscerating hog carcasses, placed his work boot over a clean and sanitized belt used to transport viscera to the DVFA inspection area. The boot was not cleaned and sanitized between each evisceration process and the evisceration stand was not a sanitary surface. The work stand was not constructed in a manner to prevent the work boot from being positioned over the belt.
    - The DVFA veterinary inspector performing pre-operational sanitation verification inspection in the slaughter area identified approximately 20 product contact and non-product contact deficiencies that the establishment failed to identify on their pre-operational sanitation report.
    - The establishment did not follow written procedures in their pre-operational and operational SSOP by failing to identify and fully describe sanitation deficiencies, proper disposition of contaminated product, restore sanitary conditions and prevent recurrence of contamination of direct product contact surfaces.

- One establishment was not maintaining daily records sufficient to document the implementation and monitoring of the establishment's SSOP. For example:

    - Sanitation records documenting the implementation and monitoring of the SSOP did not reflect the actual condition of the establishment observed during preoperational sanitation conducted by the DVFA inspector and records generated by the DVFA inspector.

- Four establishments did not meet the requirements of EC Directive 64/433 and were not operated and maintained in a manner sufficient to prevent creation of insanitary conditions and to ensure that product is not adulterated. For example:

    - A production worker picked up product that dropped onto the floor and placed the product onto a reconditioning table and proceeded to his work station without washing his hands.
    - Condensation was observed over a brine tank in the brine preparation and storage room. There was a lid covering the tank with areas open to the condensate. Rusty pipe fittings were located over openings in the lid covering the brine tank. The lid was covered with rusty water and rust stains.
    - Establishment employees working in contact with product, food contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms and equipment outside the establishment and then returning to production areas inside the establishment without changing work uniforms or cleaning and sanitizing equipment. Establishment employees changed into work uniforms, exited the employee welfare area and walked outside, approximately 50 feet, to the equipment room. The same employees received knives, scabbards, stainless steel mesh gloves and mesh aprons, exited outside the building and walked approximately 50 feet to enter production areas. During the onsite audit of the establishment, even though workers wore plastic aprons, establishment workers were observed to handle edible product and the product would come into contact with their work clothes.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Denmark's legislation.

The auditor was informed that relevant FSIS regulations had been transposed into Danish legislation. This allows legal sanctions to be issued to establishments that do not comply with third country export requirements. The specific Danish Order number, 282, April 18, 2005, has been replaced by Order number 45 of January 18, 2007.

6.2 Government Oversight

6.2.1 CCA Control Systems

There are two levels of supervision over the official activities of all government employees in certified establishments:

The Danish Veterinary and Food Administration (DVFA) is the Central Competent Authority (CCA) under the Ministry of Family and Consumer affairs (MFCA) in Copenhagen. There are 12 Divisions under the Danish Veterinary and Food Administration as follows:

Animal Health Division; Control Coordination Division; International Trade Division; Division for Microbiological Food Safety, Hygiene and Zoonoses Control; Division for Chemical Food Safety, Animal Welfare and Veterinary Medical Products; Division for Food Quality, Technology and Marketing Practices, Division for Nutrition, Communication Division, Division for Legal Affairs and International Coordination, Finance and Accounts Division, Human Resources Division, IT Division.

The International Trade Division (ITD) is responsible for control of trade, including the import and export of live animals, semen, eggs, embryos, food and non-food products, travel with pets, border control, export certificates, lists of enterprises certified for exports to specific third countries, planning of inspection visits and international inspection procedures, audit of USA-certified meat enterprises, coordination of the Administration's activities in Greenland, including the Greenland Veterinary Service, and EU veterinary agreements with third countries.

The External Audit Unit of DVFA conducts the administrative audit of control and inspection in accordance with the Danish Food Act. The Audit Unit draws up audit reports for the Veterinary and Food Control Committee (VFCC). These reports form the basis of the Veterinary and Food Control Committee's evaluation of the control undertaken. The Audit Unit is an autonomous unit that reports directly to the VFCC and administratively to the Executive Director of the DVFA. The Audit Unit under ITD carries out central supervision of the regional DVFA personnel and is involved in periodic audits and approval of U.S. certified establishments.

The responsibilities of periodic supervisory reviews in the US certified establishments are shared as follows: The Regional Veterinary and Food Administration Centers (RVFAC) carries out monthly supervisory reviews in the U.S. certified establishments. The Audit Unit under ITD carries out central supervision of the regional DVFA personnel (RVFAC) and is involved in periodic audits and approval of U.S. certified establishments with the following frequencies: Four audits in slaughter establishments, three audits in processing establishments and two audits in cold stores per year.

The Control Coordination Division (CCD) is responsible for control principles and strategies, and general control rules, food and veterinary controls in general, including the development of tools for the Regional Veterinary and Food Control Centers (RVFCC) to guarantee uniform quality when performing inspections. Overall guidelines for the regional veterinary food control center' control planning, supervision of the individual inspector, guidance on general control issues, case follow-up with reference to inspection performed by the RVFCC, drawing up rules for internal control, coordination of regional laboratories and centrally coordinated laboratory projects, general rules on traceability, publication of inspection results, collection and processing of data from the control and the RVFCC. The CCD undertakes an annual supervision of each Regional Veterinary and Food Administration Centre (RVFAC) to ensure uniformity, evaluate whether inspections are performed in a satisfactory manner and in accordance with procedures, and evaluate the management of the local Control and Enforcement Offices.

DVFA has three Regional Veterinary and Food Administration Centers, RVFAC (Region North, Region South, and Region East). They have a total of 10 Control and Enforcement

Offices across the whole of Denmark. The control and enforcement offices conduct inspections of livestock and foodstuffs, from farm to fork. The control and enforcement offices' major area of work is meat control at abattoirs and meat production enterprises. The Control and Enforcement Offices have a total of 16 District Veterinary Officers in charge of the inspection in slaughterhouses and other meat establishments. Inspection visits to food enterprises include the inspection of internal control programs, hygiene, labeling, traceability of live animals, sampling for analytical control, follow-up on confirmed violations, and periodic supervisory reviews for the U.S.-certified establishments.

The Head of the Control and Enforcement Office is in charge of the supervision of the individual inspectors. However, the responsibility for the supervision of Official Veterinarians and non-veterinary technicians located at meat establishments has been delegated to the District Veterinary Officer.

The Head of the Control and Enforcement Office is responsible for the periodic (monthly) supervisory reviews at U.S.-certified meat establishments. Under his responsibility the supervisory reviews are carried out by the Regional Supervisors.

6.2.2 Ultimate Control and Supervision

The DVFA headquarters in Copenhagen has ultimate control and supervision of Denmark's meat inspection system. Although Denmark's inspection system is supervised by individual RVFAC, the DVFA develops and distributes official legislation to the RVFAC. The DVFA coordinates the implementation of inspection activities at each RVFAC and carries out training programs for the regional staff, organizes country-wide campaigns and assesses the performance of the regional units with regard to food and veterinary control by yearly visits to each unit. The DVFA transposes EC legislation and related FSIS regulations into Danish legislation with related guidelines.

The RVFAC is responsible for recommending the certification or decertification of establishments eligible to export to the United States to the DVFA headquarters in Copenhagen. The head of the International Trade Division of the DVFA is responsible for the official certification or decertification of establishments and is responsible for maintaining the official list of establishments eligible to export to the United States.

The following deficiencies in the control and supervision of Denmark's meat inspection system were observed.

- Danish Veterinary and Food Administration (DVFA) officials did not demonstrate that they have effective oversight that would facilitate accountability of the Regional Danish Veterinary and Food Administration Authority (RDVFA) inspection officials and effective supervision of inspection activities at the establishment levels.
- Regional Veterinary Supervisors for the U.S. certified establishments (RVS) did not demonstrate that they have adequate supervision over veterinary inspectors in the certified meat establishments.
- There was inadequate verification of the implementation of U.S. requirements by all three regions.

- DVFA auditing procedures were not effective.
- The periodic supervisory reviews that were conducted, for seven of the eight establishments audited, did not reflect actual establishment conditions.

6.2.3 Assignment of Competent, Qualified Inspectors

The RVFAC is responsible for the initial hiring, training and payment of veterinarians and non-veterinary technicians. Veterinarians receive classroom training in public health and food inspection as part of their normal veterinary degree course of study. Veterinarians receive on-the-job training at the establishment level. Non-veterinary technicians often have experience as a slaughterhouse worker. They are educated at the Danish Meat Trade College. The course consists of 18 weeks of theoretical training and 15 weeks of practical training. On-going training needs are determined and scheduled by the official veterinarian or the head veterinarian through consultation with the RVFAC. Special emphasizes is placed on HACCP, SSOP and Supervision training.

A yearly performance conference for each DVFA employee is required by Danish law. There are written guidelines describing how the performances conferences should be conducted. The performance conferences are documented and retained by the supervisor of the employee in a confidential personnel file.

Quality supervision consisting of an administrative component and a program component is conducted for Veterinarians and non-veterinary technicians at least once every two years. The quality supervision report is maintained at the RVFAC. This is required by an official contract between the RVFAC and the DVFA.

The RVS develops a yearly supervision plan to be conducted for each U.S.-certified establishment. The plan includes evaluation of the supervision in the last month with recommendations; follow up with issues identified in the previous reports, audit reports, special subjects, legislation and checklists.

- It appeared that the formal training in HACCP/Pathogen Reduction was not sufficient to ensure enforcement of U.S. requirements.

6.2.4 Authority and Responsibility to Enforce the Laws

The DVFA has the legislative authority and the responsibility to enforce FSIS requirements, but not all FSIS requirements were enforced. For example:

- Seven of the eight establishments audited received Notices of Intent to Delist (NOIDs) for inadequate implementation of HACCP, SSOP, SPS, and EC Directive 64/433 requirements
- In seven establishments, SSOP requirements were not met.
- In seven of the eight establishments audited, SPS and EC Directive 64/433 requirements were not met.
- In seven establishments, HACCP implementation requirements were not met.

- In seven establishments, the periodic supervisory reviews performed by the CCA and Regions did not adequately verify the implementation of HACCP, SSOP, SPS, and EC Directive 64/433 requirements.
- In all six slaughter establishments audited, the DVFA inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that carcasses were not contaminated with fecal material, ingesta, or milk after the final rail inspection station.
- In seven establishments, DVFA inspection officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records, and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment.
- In three establishments, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to prevent recurrence of direct contamination or adulteration in the pre-operational and operational sanitation verification records.
- In seven establishments, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations, and records reviews.
- In one establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan for the second shift operation.
- In three establishments, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when deviations from a CL occurred.
- In two establishments, the on-going verification activities were not conducted to ensure that the monitoring was implemented effectively for the 2nd shift operations.

6.2.5 Adequate Administrative and Technical Support

The DVFA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate Denmark's inspection system.

6.3 Headquarters and Regional Offices Audit

The auditor conducted a review of inspection system documents at the headquarters of the DVFA located in Copenhagen. The auditor also conducted a review of records at the RVFAC located in Vejle for the purpose of determining the supervisory structure of the region and to review records pertinent to establishments included in the audit of Denmark's meat inspection system. Other records reviewed focused on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- Training programs for inspection personnel.

- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with disease conditions and of inedible and condemned materials.
- Export product inspection and control.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of eight establishments. Six were slaughter establishments, one was a processing establishment and one was a cold storage facility. No establishments were delisted by Denmark. Seven establishments received a Notice of Intent to Delist (NOID) for inadequate implementation of HACCP, SSOP, SPS, and EC Directive 64/433 and lack of enforcement requirements. These seven establishments may retain their certifications for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishments were reviewed.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

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

One Regional Residue and Microbiology Laboratory, located in Ringsted was audited. No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Denmark's inspection system had controls in place for all aspects of facility and equipment sanitation, the prevention of potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

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

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in the establishments audited were found to meet the basic FSIS regulatory requirements, with the following exceptions:

- In seven establishments, establishment officials were not routinely evaluating the adequacy and effectiveness of the SSOP to prevent direct product contamination or adulteration.
- In seven establishments, pre-operational and operational sanitation SSOP implementation deficiencies were found:
  - Product residues, pieces of fat and detergent residue from the previous day's operations were observed on food-contact surfaces of plastic conveyor belts and carcass splitting saws in the primal cut-up room.
  - Pieces of fat from the previous day's operations were observed on food-contact surfaces in a packaging machine.
  - Product residues from the previous day's operations were observed on food-contact surfaces in the swine slaughter room (dehairing equipment, a plastic conveyor belt, a carcass splitting saw, a shovel for handling edible product, sanitizers, and employees' metal mesh gloves).
  - Fat residues from the previous day's operations were observed on food-contact surfaces in the cooler.
  - Pieces of fat and detergent residues were observed in metal bins, ready for use, in the edible fat melting and boning rooms.
  - Condensate was dripping onto tree hooks from overhead pipe, electrical cables, and a rail in the equipment washing room. The hooks had been cleaned and sanitized and were ready to be used for edible product.
  - Condensate was dripping from an overhead pipe onto hog carcasses at the entrance to the cooler.
  - Pieces of fat and blood were observed on viscera pans, ready for use, in the slaughter room.

- Fore legs of swine carcasses were contacting the working platforms and employees' boots at the eviscerating stations in the slaughter room.
- Product residues and fat were observed on employees' metal mesh gloves, ready for use, in the cut-up room.
- Edible product was contacting non-food contact surfaces a (conveyor belt) in the cut-up room.
- Fat, blood, and grease were observed on offal hooks, ready for use, in the slaughter room.
- Water from a sanitizer was falling onto fore-legs of carcasses during sanitization of equipment at the carcass eviscerating station in the slaughter room.
- In six establishments, deficiencies identified during pre-operational and operational sanitation SSOP were not adequately described on the records and did not document the corrective actions properly to prevent recurrence of direct product contamination or adulteration.
- Water was splashing from the floor onto the inverted food-contact surfaces of the viscera pan conveyor in the slaughter room.

9.2 EC Directive 64/433

In seven of the eight establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented. The following deficiencies were noted.

- Seven of the eight establishments audited did not meet SPS and EC Directive 64/433 requirements: For example
  - An accumulation of fat residue from the previous day's operations was on beams and pipes in the swine dehairing room.
  - Several doors between the equipment washing room, processing rooms, and packaging rooms opened upward, and wet floors below the doors presented a potential for water dripping onto exposed edible product and employees' clothes while passing through these doors.
- Seven of the eight establishments audited did not meet the requirements of SPS and EC Directive 64/433 and were not operating and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product was not adulterated. For example:
  - Wet loose plastic was observed on the upper panel window through which the clean bins were passing through after washing and sanitizing.
  - An accumulation of fat residue and black grease from the previous day's operation was observed on supports, beams, and the inner side of the plastic protective coverings on both sides of a rail in the swine dehairing room.
  - Flaking paint was observed on a wall behind the refrigeration unit in the offal cooler.
  - An opening in the outside wall of the pallet storage room was not sealed properly to prevent the entry of insects, rodents, and other vermin.
  - Several outside doors in the establishment were not sealed properly to prevent the entry of insects, rodents and other vermin.

- In two establishments, packaging supplies were kept in the dry storage room in a manner that prevented the inspection of dry storage room for the presence of pest or insanitary conditions. For example:
  - The storage racks were not high enough and were stored against the walls or directly on the floor. Dead insects, dirt, and cobwebs were also observed in the room. Numerous pieces of used equipment and other non- packaging materials were stored directly on the floor. Open spaces at the bottom of a wall were not sealed properly to prevent the entry of insects, rodents, and other vermin.
- In four establishments, beaded condensate was observed on overhead pipes, rails, refrigeration units, and ducts in the coolers.
- In two establishments, the potable water storage tanks were not sealed properly to prevent entry of vermin and dust. Dead insects, cobwebs, rust, and an accumulation of dirt were observed inside the water tank lid.
- In one establishment, due to inadequate floor drainage at the container washing machine, water on the floor was falling onto containers waiting for cleaning in the room below.
- In one establishment, due to inadequate floor drainage, water had accumulated in the swine brisket opening cabinet.
- In one establishment, edible and inedible product containers, ready for use, were commingled in a container storage room. In another establishment, edible offal and pet food bins were commingled in the cooler.
- In two establishments, product was not adequately protected from adulteration during processing, storing, and transporting. For example:
  - Edible product was not properly protected from any fallout from the overhead catwalk in the edible fat room.
  - The bottoms of plastic strip curtains were contacting employees' boots and clean clothes, edible product containers, and exposed edible products when they were passing through the doors of production room.
  - An accumulation of fat residue from the previous day's operation was observed inside of the exhaust system of a washing machine and rusty drying equipment over the containers cleaning line in the washing room.
  - Fat residue was observed inside a cabinet for drying viscera pans in the slaughter room.
- In one establishment, an employee was observed picking up pieces of meat from non-food contact surfaces and saving them in a container for edible product and, without washing his hands, handling edible product in the packaging room.

Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, procedures for sanitary handling of returned and reconditioned product. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

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

One establishment audited was a cold storage facility that conducted freezing and storage of boxed pork products for export to the United States and was not required to have developed a HACCP program.

The HACCP programs were reviewed during the on-site audit of seven establishments. Although the HACCP plans in the seven establishments were found to meet the basic FSIS regulatory requirements, it was found that six of the seven establishments had not adequately implemented their HACCP plans. Examples of these deficiencies include:

- In six of the seven establishments, one or more HACCP problems were observed. For example:
- In two establishments, the monitoring procedures were not described adequately for the Critical Control Points (CCP) to ensure compliance with the Critical Limit (CL) in the HACCP plan.
- In one establishment, the monitoring procedures were not conducted as specified in the HACCP plan for the second-shift operation.
- In two establishments, when deviations from CLs occurred, establishment employees failed to take corrective actions. There were no records that documented that:
  - The cause of the deviation was eliminated.
  - The CCP was brought under control after corrective action was taken.
  - Measures to prevent recurrence were established.
  - No product that was adulterated as a result of the deviation entered commerce.
- In four establishments, the HACCP plans did not include supporting documentation for the verification frequencies to ensure that the monitoring was implemented effectively.

- In two establishments, the on-going verification activities were not conducted to ensure that the monitoring for the second shift operation was implemented effectively.
- In three establishments, the monitoring records for CLs were not signed or initialed each time and/or did not include the findings when actual observations were made.
- In three establishments, the employees did not record the times, signatures or initials when the on- going verification activities were performed.

11.3 Testing for Generic *E. coli*

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

1. Denmark establishments use a gauze swab sampling tool.
2. Private microbiology laboratories use an AOAC approved NMKL method or AOAC Petrifilm method to analyze samples for generic *E. coli.*

Six of the eight establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* in lieu of *Enterobacteriaceae* and total viable count and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in all six of the slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

During this audit, no establishment eligible for export to the United States was producing ready-to-eat products so testing for *Listeria monocytogenes* was not applicable.

11.5 EC Directive 64/433

In seven of the eight establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented.

12. RESIDUE CONTROLS

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

The Regional Veterinary Food Control Authority Residue Laboratory, located in Ringsted was audited. No deficiencies were noted.

Denmark's National Residue Control Program for 2007 was being followed and was on schedule.

12.1 EC Directive 96/22

No deficiencies were noted in the Residue Laboratory.

12.2 EC Directive 96/23

No deficiencies were noted.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

All establishments were staffed with full-time veterinarians and non-veterinary inspectors. Continuous daily inspection was provided for all certified slaughter establishments. In processing establishments, inspection was carried out daily on each shift when U.S.-destined products were produced. In U.S.-certified cold stores inspection was carried out weekly.

13.2 Testing for *Salmonella*, *Salmonella* Performance Standards

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

1. Establishments take the official *Salmonella* Performance Standards samples.

- The DVFA provides a clearly written sampling plan with instruction for sample collection and processing.
- Sample verification testing is performed by an official DVFA veterinarian once every week and the sample is analyzed in the Regional Veterinary Food Control Authority Microbiology Laboratories.
- Test results are provided directly to the government veterinarian.
- NMKL method is used to analyze samples.

2. *Salmonella* testing strategy

- The DVFA uses a continuous, ongoing sampling program. Each U.S.-certified slaughter establishment collects one sample per production day, grouped in sample sets of 55 samples and uses FSIS Performance Standards and enforcement procedures.
- The DVFA testing program has statistical criteria for evaluating test results.

3. A gauze pad sampling tool is used.

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

Salmonella testing was properly conducted in all six slaughter establishments audited.

13.3 Verification Testing Program for Ready-to-Eat Product.

No establishment was audited exporting ready-to-eat product to the United States during this audit.

13.4 Species Verification

Species verification testing was being conducted as required in the seven establishments audited.

13.5 Periodic Supervisory Reviews

During this audit it was found that in all establishments visited, periodic supervisory reviews of certified establishments were being performed and documented as required.

- In seven establishments, the periodic supervisory reviews performed by the CCA and Regions did not adequately verify the implementation of HACCP, SSOP, SPS, and EC Directive 64/433 requirements.

13.6 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market with the following exception:

- In all six slaughter establishments audited, the DVFA inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that carcasses were not contaminated with fecal material, ingesta or milk after the final rail inspection station.
- In seven establishments, DVFA inspection officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records, and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment.
- In three establishments, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to prevent recurrence of direct contamination or adulteration in the pre-operational and operational sanitation verification records.

- In seven establishments, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations, and records reviews.
- In one establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan for the second shift operation.
- In three establishments, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when deviations from a CL occurred.
- In two establishments, the on-going verification activities were not conducted to ensure that the monitoring was implemented effectively for the 2nd shift operations.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

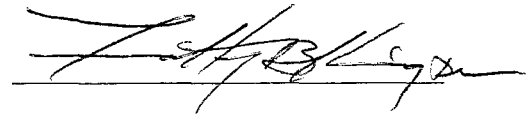
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on May 11, 2007, in Copenhagen with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for Faizur R. Choudry, DVM
Senior Program Auditor



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Holstebro, Denmark	04/26,27/07	15	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	X
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 15, Danish Crown, Holstebro, Denmark, April 26-27, 2007 Slaughter/processing

10/51. a) Product residues, pieces of fat, and detergent residue from the previous day's operations were observed on food-contact surfaces (plastic conveyor belts and carcass-splitting saws) in the primal cut-up room. The establishment personnel took corrective actions. **b)** Fore-legs of hog carcasses were contacting employees' boots at the evisceration station and employees' clothes in the slaughter room. **c)** Hams were contacting galvanized stands which were recently painted in the processing room. [Regulatory references: 9 CFR 416.13 and 416.17]
11/51. Establishment personnel were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. Records indicated that no operational sanitation deficiencies had been identified by the establishment employees since January 2007. [9 CFR 416.14 and 417.17]
13/51. The establishment did not adequately describe the deficiencies identified on the daily operational SSOP reports. [9 CFR 416.16 and 416.17]

22/51. The establishment personnel did not record the times when the on-going verification activities were performed. Some entries on the monitoring record were not signed or initialed by the establishment employee making the entries. [9CFR 417.5(a)(3) and (b) and 417.17]

39/51/56. a) Three outside doors in the establishment were not sealed properly to prevent the entry of insects, vermin and rodents. [9 CFR 416.2(a)(b) and EEC C/D 64/433, Annex 1, Chapter II.2(m)]
b) An accumulation of fat residue and black grease from the previous day's operations was observed on supports, beams, and the inner side of the plastic protective coverings on both sides of rail in the swine dehairing room.
c) Packaging supplies were kept in the dry-storage room in a manner that prevented the inspection of dry storage room for the presence of pests or insanitary conditions. For example, the storage racks were not high enough and were stored against the walls or directly on the floor. Dead insects, dirt, and cobwebs were also observed in this room. Numerous pieces of used equipment and other non-packaging materials were stored directly on the floor. Open spaces at the bottom of a wall were not sealed properly to prevent the entry of insects, vermin, and rodent. [9 CFR 416.2(a) (b) and EEC C/D 64/433, Annex 1, Chapter II.2 (m)]
42/51/56. The potable-water storage tank was not sealed properly to prevent the entrance of dust, insects, and other vermin. Dead insects, cobwebs, rust, and accumulations of dirt were observed inside the water tank lid. [9 CFR 416.2(e)(3) and C/D 64/433/EEC Annex 1 Chapter 1 and 11]

51. a) In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that carcasses were not contaminated with fecal material, ingesta, or milk on swine carcasses after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA inspection officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and no deficiencies were observed by DVFA inspection officials. Records indicated that the inspection officials had conducted two pre-operational and five operational sanitation SSOP verifications per month. [9 CFR 416.17]

c) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that they met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations and records reviews. [9 CFR 417.8]

d) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction trainings. [9 CFR 417.7]

51/57. Periodic supervisory reviews were routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R. Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Steff-Houlberg Ronne, Denmark	05/03/07	22	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 22, Danish Crown; Ronne, Denmark, May 3, 2007 Slaughter/processing

10/51. **a)** Edible product was contacting non-food-contact surfaces (a conveyor belt) in the cut-up room. **b)** Hams were contacting the walls in the cooler. **c)** Carcasses were contacting employee's clothes in the carcass primal cut-up room. **d)** Fore-legs of hog carcasses were contacting a working platform at the bung dropping station in the slaughter room. **e)** Water from a sanitizer was falling onto the carcasses fore-legs during sanitization at the eviscerating station. **f)** Fat, blood, and grease were observed on conveyor offal hooks ready for use, in the slaughter room. **g)** Pieces of fat and meat from the previous day's operations were observed on food-contact surfaces in a packaging machine. [Regulatory references: 9 CFR 416.13 and 416.17]

11/51. Establishment personnel were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. Monitoring records indicated that no deficiencies had been identified during pre-operational sanitation by the establishment personnel since January 2007. [9 CFR 416.14 and 417.17]

13/51. Establishment employees were not adequately describing some deficiencies or documenting some corrective actions taken in the operational sanitation SSOP reports. [9 CFR 416.16 and 416.17]

22/51. The monitoring records for Critical Limits (CL) did not include the actual observations. The monitor was entering check marks for observation of temperatures, whereas, according to the HACCP plan, he was required to record the actual temperatures monitored in each room. Some entries on establishment monitoring records did not include actual times and were not signed or initialed by the establishment employee making the entries. [9 CFR 417.5(a) (3) and (b) and 417.17]

39/51/56. **a)** The packaging supplies were kept in the dry storage room in such a manner which will prevent the inspection of dry storage room for the presence of pest or insanitary conditions. For example, the storage racks were not high enough and were stored against the walls or directly on the floor. Dead insects, dirt, and cobwebs were also observed in this room. Open spaces at the bottom of all windows in the dry storage room were not sealed to prevent the entry of insects, vermin, and rodents. [9 CFR 416.2(a) (b) and EEC C/D 64/433, Annex 1, Chapter II.2 (m)] **b)** Flaking paint was observed on a wall behind the refrigeration unit in the offal cooler. [9 CFR 416.2(b) and 416/17 and C/D 64/433/EEC Annex 1 Chapter II (2)]

41/51/56. Beaded condensate was observed on a refrigeration unit and pipes in one cooler. [9 CFR 416.2 (d) 416.17 & EEC C/D 64/433 of June 26, 1964. Annex1 Chapter1]

45/51/56. **a)** Edible and inedible product containers ready for use, were commingled in a container-storage room. **b)** An accumulations of fat and rust were observed on the refrigeration unit in the offal cooler. [9 CFR 416.3 (a) (d) and 416.17 and EEC C/D 64/433 of June 26, 1964. Annex1 Chapter1II]

46/51/56. **a)** The bottoms of plastic strip curtains were contacting employees' boots and clean clothes, edible product containers, and exposed edible products when they were passing through the doors of production room. **b)** An accumulation of fat residue from the previous day's operations was observed inside of the exhaust system of a washing machine and rusty drying equipment over the containers cleaning line in the washing room. **c)** An accumulation of fat and extraneous materials were observed on the protective covering over the carcass evisceration line in the slaughter room. **d)** Fat residue was observed inside a cabinet for drying viscera pans in the slaughter room. [9 CFR 416.4(d) and EEC 64/433, Annex 1, Chapter III (3)]

47/51/56. An employee was observed picking up pieces of meat from non-food contact surfaces (rollers) and saving them in a container of edible product and, without washing his hands, handling edible product in the product packaging room. [9 CFR 416.5(a) and EEC C/D 64/433 of June 26, 1964. Annex1 Chapter 1II (3)]

51. **a)** In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that carcasses were not contaminated with fecal material, ingesta, or milk on swine carcasses after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA inspection officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and no deficiencies were observed by DVFA inspection officials. Records indicated that the inspection officials had conducted one pre-operational and two operational sanitation SSOP verifications per month. [9 CFR 416.17]

c) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, and onsite observations and record review. Records indicated that inspection officials had conducted only one direct observation at a CCP and only one record review since January 2007. [9 CFR 417.8]

d) In establishment, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when a deviation from a CL occurred. [9 CFR417.8(c)]

e) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction training. [9 CFR 417.7]

51/57. Periodic supervisory audits were routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faiz R Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Ringsted, Denmark	04/19, 20/07	25	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 25, Danish Crown, Ringsted, Denmark; April 19 -20/2007 Slaughter/processing

10/51. a) Pieces of fat and blood were observed on food-contact surfaces of conveyor viscera pans in the slaughter room. **b)** Fore-legs of swine carcasses were contacting workers' platforms and boots at evisceration stations in the slaughter room. Establishment management took corrective actions temporarily in some cases. [Regulatory references: [9 CFR 416.13 and 416.17]

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. Records indicated that no preventive measures were taken for the deficiencies identified during pre-operational and operational sanitation monitoring. [9 CFR 416.14 and 417.17]

13/51. The establishment was not documenting preventive measures for the recurrence of direct product contamination or adulteration in the pre-operational and operational sanitation monitoring records. [9 CFR 416.16 and 416.17]

18/51. The establishment was not conducting the monitoring procedures as specified in the HACCP plan for the 2nd shift processing operation. [9 CFR 417. 2(c) (4) and 417.8]

20/51. The establishment failed to take corrective actions when product temperature deviations occurred in the cooler. There were no records documenting that: (1) the cause of the deviation was eliminated, (2) the CCP was brought under control after corrective action was taken, (3) measures to prevent recurrence were established, and (4) no product that was adulterated as a result of the deviation enters commerce. Further, the establishment had written in the HACCP plan that, if a temperature deviation occurs and stays above the critical limit for only one hour, no corrective action is necessary. [9 CFR 417.3(a) and 417.8]

22/51. a) The establishment's HACCP plan did not include supporting documentation for the verification frequency to ensure that the monitoring was implemented effectively. **b)** The establishment was not performing verification procedures for the 2nd shift processing operation. **c)** The monitoring records for Critical Limits (CL) was not signed or initialed each time by the establishment employee making the entry (the monitor was identifying his initial or signature with a number assigned by the establishment). [9 CFR 417.2(c)(7) and 417.5(b) and 417.17]

41/51/56. Beaded condensate was observed on overhead pipes in four carcass coolers. [9 CFR 416.2 (d) 416.17 & EEC C/D 64/433 of June 26, 1964. Annex1 Chapter1]

51. a) In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that swine carcasses were not contaminated with fecal material, ingesta, or milk after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the effectiveness of measures taken to prevent recurrence of direct product contamination or adulteration in the operational sanitation verification records. [9 CFR 416.17]

c) In establishment, DVFA officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and only minor deficiencies were observed by the inspection officials. Records indicated that the inspection officials had conducted three pre-operational sanitation SSOP verifications for the slaughter room since January 2007. [9 CFR 416.17]

d) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations and records reviews. Records indicated that inspection officials had conducted CCP verification once since January, 2007. [9 CFR 417.8]

e) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan for the 2nd shift processing operation.
[9 CFR 417.8]

f) In establishment, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when a deviation from the CL for CCP 7c (temperature) occurred. [9 CFR 417.8(c)]

g) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction training. [9 CFR 417.7]

51/57. Periodic supervisory reviews were routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur. R. Choudry, DVM	Faiz R Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Rodding, Denmark	04/26/07	318	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	X
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 318 Danish Crown, Rodding, Denmark; April 26, 2007 Processing

10/51. a) Fat residue from the previous day's operations was observed on food-contact surfaces in the cooler. **b)** Pieces of fat were observed on employees' metal gloves, ready for use, in the boning rooms. [Regulatory references: 9CFR 416.13 and 416.17]

39/51/56. a) An accumulation of fat residue from the previous day's operations was observed on a refrigeration unit in one cooler.
b) Gaps at both sides of the entrance door to the dry storage room were not sealed properly to prevent the entrance of rodents and other vermin. [9 CFR 416.2(b) and 416/17 and C/D 64/433/EEC Annex 1 Chapter II (2)]

41/51/56. Beaded condensate was observed on a refrigeration unit and a duct in one cooler. [9 CFR 416.2 (d) 416.17 & EEC C/D 64/433 of June 26, 1964. Annex1 Chapter1]

42/51/56. The potable-water storage tank was not sealed properly to prevent the entrance of dust or insects and other vermin. Dead insects, cobwebs, rust, and accumulations of dirt were observed on a platform inside the water tank. [9CFR 416.2(e)(3) and C/D 64/433/EEC Annex 1 Chapter 1 and 11].

51. a) In establishment, DVFA inspection officials were not verifying the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and no deficiencies had been observed by DVFA inspection officials. Records indicated that inspection officials had conducted only four pre-operational and two operational sanitation SSOP verifications since January 2007.
[9 CFR 416.17

b) In establishment, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the effectiveness of measures taken to prevent recurrence of direct product contamination or adulteration in the pre-operational and operational sanitation verification records. [9 CFR 416.17]

c) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, and onsite observations and record reviews. Records indicated that inspection officials had conducted only one direct measurement at a CCP since January 2007. [9 CFR 417.8]

e) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction training.
[9 CFR 417.7]

51/57. Periodic supervisory reviews were routinely conducted by the District Veterinarian but the HACCP plan was not adequately verified. [9 CFR 416.17]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States. Establishment 318 had been issued a Notice of Intent to Delist (NOID) for failure to implement SSOP and HACCP plan, during the last audit on July 17, 2005.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R. Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Vojens, Denmark	04/25/07	319	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 319, Danish Crown, Vojens, Denmark; April 25, 2007 Slaughter/processing

10/51. a) Product residues, grease, and fat from the previous day's operations were observed on food-contact surfaces in the swine slaughter room (de-hairing equipment, a plastic conveyor belt, a carcass-splitting saw, a shovel for handling edible product, sanitizers, and employees' metal mesh gloves). Establishment officials took corrective actions, although slowly. **b)** Condensate, from overhead pipes and ceilings was falling onto edible product (offal) in the cooler. **c)** Pieces of fat and dried blood were observed on employees' metal gloves, ready for use, in the cut-up room. **d)** Condensate from an overhead pipe and a duct was falling onto offal and viscera pans, ready for use, in the slaughter room. **e)** Pieces of fat, blood, and extraneous material were observed on viscera pans, ready for use in the slaughter room. [Regulatory references: 9 CFR 416.13 and 416.17]

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. [9 CFR 416.14 and 417.17]

13/51. The establishment did not adequately describe the deficiencies identified on the daily pre-operational and operational SSOP and did not document any corrective actions taken. [9 CFR 416.16 and 416.17]

18/51. The establishment did not describe the monitoring procedures for Critical Control Points (CCP) adequately in the HACCP plan to ensure compliance with the Critical Limits (CL). [9 CFR 417.2(c)(4) and 417.17]

22/51. a) The establishment personnel did not record the times when the on-going verification activities were performed. **b)** The establishment had no documentation supporting the on-going verification frequencies to ensure that the monitoring was implemented effectively. [9CFR 417.5(a)(3) and 417.17]

39/5/561. a) An accumulation of fat residue from the previous day's operations was observed on rails, pipes, and ceilings in the swine de-hairing room. [9 CFR 416.2(b) and 416/17 and C/D 64/433/EEC Annex 1 Chapter II(2)]
b) An opening in the outside wall of the pallet storage room was not sealed properly to prevent the entry of insects, rodents, and other vermin. [9 CFR 416.2(a)(b) and EEC C/D 64/433, Annex 1, Chapter II.2(m)]

51. a) In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that swine carcasses were not contaminated with fecal material, ingesta, or milk after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment. DVFA inspection officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures (looking over the shoulder), and no deficiencies were observed by DVFA inspection officials. Records indicated that the inspection officials had conducted two pre-operational and four operational sanitation SSOP verifications per month since January 2007. [9 CFR 416.17]

c) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations, and records reviews. Records indicated that inspection officials had conducted one direct observation at a CCP, one records review, and one review of the instrument used for the calibration of process monitoring since January 2007. [9 CFR 417.8]

d) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction training. [9 CFR 417.7]

51/57. Periodic supervisory reviews had been routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R. Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Horsens N, Denmark	04/30/07	320	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	X
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 320 Danish Crown, Horsens N, Denmark April 30, 2007 Slaughter/processing

10/51. a) Edible products were contacting the non-food-contact surfaces at the product-packaging machines. **b)** Pieces of meat and fat were observed in metal bins, ready for use, in the cleaning room. **c)** Condensate was dripping onto tree hooks from overhead pipes, electrical cables, and a rail in the equipment washing room. The hooks had been cleaned and sanitized and were ready to be used for edible product. **d)** Fat and detergent residues were observed in metal bins, ready for use, in the edible fat melting room and the boning room. **e)** Black grease was observed on a rail guide at the entrance to the cut-up room. **f)** Fore-legs of swine carcasses were contacting employees' clothes in the slaughter room. **g)** Water was splashing from the floor onto the inverted food-contact surfaces of the viscera pan conveyor in the slaughter room. **h)** Blood was observed on the head and tongue pans conveyer, ready for use, in the slaughter room. **i)** Pieces of fat from the previous day's operations were observed on food-contact surfaces in the packaging machine. [Regulatory references: 9 CFR 416.13 and 416.17]

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. [9 CFR 416.14 and 417.17]

13/51. The establishment did not adequately describe the deficiencies identified on the daily operational sanitation SSOP reports. [9 CFR 416.16 and 416.17]

20/51. The establishment failed to take corrective actions when deviations from Critical Limits (CL) 7C (room temperature) and CL 88C (temperature for edible fat melting) occurred. There were no records that documented that (1) the cause of the deviation was eliminated; (2) the the CCP was brought under control after corrective action was taken; (3) measures to prevent recurrence were established, and (4) no product that was adulterated as a result of the deviation entered commerce. The establishment's HACCP Plan stated that if a temperature deviation occured and stayed above the critical limit for less than one hour, no corrective action would be necessary. [9 CFR 417.3(a) and 417.8]

22/51. a) The establishment did not have supporting documentation for the verification frequency in the HACCP plan. [9 CFR 417.2(c)(7) and 417.17] **b)** The establishment personnel did not record the actual times when the on-going verification activities were performed. [9 CFR 417.5(a)(3) and (b) and 417.17] **c)** The establishment was not conducting on-going verification activities to ensure that the monitoring for the 2nd shift operation was implemented effectively. [9 CFR 417.4(2) and 417.17]

39/51/56. Wet, loose plastic was observed on the upper panel window through which the clean bins were passing through after washing. [9 CFR 416.2(b) and 416/17 and C/D 64/433/EEC Annex 1 Chapter II(2)]

42/51/56. a) Due to inadequate floor drainage, water had accumulated in the swine brisket opening cabinet. **b)** Due to inadequate floor drainage at the container washing machine, water on the floor was falling onto containers waiting for cleaning in the room below. [9 CFR 416.2(e)(4) and 416.17 and C/D 64/433/EEC Annex 1 Chapter I(1)(m)]

45/51/56. Edible offal and pet food bins were commingled in the cooler. [9 CFR 416.3(d) and 416.17 and C/D 64/433/EEC Annex 1 Chapter III]

46/51/56. Edible product was not properly protected from any fallout from the overhead catwalk in the edible fat room. [9 CFR416..4(d) and 416.17 and C/D 64/433/EEC Annex 1 Chapter I(1)]

51. a) In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that swine carcasses were not contaminated with fecal material, ingesta, or milk after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the effectiveness of measures taken to prevent recurrence of direct product contamination or adulteration in the operational sanitation verification records. [9 CFR 416.17]

c) In establishment, DVFA officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken, and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and only minor deficiencies were observed by DVFA inspection officials. Records indicated that the inspection officials had conducted pre-operational sanitation SSOP verification one per month. [9 CFR 416.17]

d) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations, and records reviews. Records indicated that inspection officials had conducted only one direct observation at a CCP, only one records review, and only one calibration of process monitoring instrument review in this two-shift operations since January, 2007. [9 CFR 417.8]

e) In establishment, DVFA inspection officials did not have adequate HACCP/Pathogen Reduction training. [9 CFR 417.7]

f) In establishment, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when deviations occurred for CL 7C (room temperature) and 88C (edible fat melting temperature). [9 CFR 417.8(c)]

51/57. Periodic supervisory reviews were routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tican A.M.B.A Thisted, Denmark	04/24/07	338	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	X
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment 338 Tican A.M.B.A., Thisted, Denmark April 24, 2007 Slaughter/processing

10/51. a) Product residues from the previous day's operations was observed on many food-contact surfaces of the dehairing equipment and employees' metal mesh gloves in the swine slaughter room. Establishment officials took corrective actions. **b)** Condensate from an overhead pipe, a wall, and an upper panel of a window was dripping onto the cleaned/sanitized bins in the equipment washing room. **c)** The hind legs of swine carcasses were contacting a black greasy rail and plastic protective coverings when they were entering the carcass cooler from the slaughter room. **d)** Condensate was dripping from an overhead pipe onto the carcasses at the entrance to the cooler. **e)** Condensate was dripping from an overhead pipe and sanitizers onto viscera pans, ready for use, in the slaughter room. **f)** Pieces of fat and blood were observed on viscera conveyor pans, ready for use in the slaughter room. [Regulatory references: 9 CFR 416.13 and 416.17]

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination or adulteration. Records indicated that every day several SSOP deficiencies were identified during pre-operational sanitation monitoring by establishment employees and each time the same preventive measures were documented. [9 CFR 416.14 and 417.17]

13/51. The establishment did not adequately describe the deficiencies identified on the daily pre-operational and operational sanitation SSOP records and did not document the corrective actions properly for the deficiencies identified to prevent recurrence of direct product contamination or adulteration. [9 CFR 416.16 and 416.17]

18/51. The establishment's HACCP plan did not adequately list the monitoring procedures for Critical Control Point (CCP) 2 to ensure compliance with the Critical Limit (CL). [9 CFR 417.2(c)(4) and 417.17]

22/51. a) The monitoring records for Critical Limits did not include the entries for the actual observations; e.g., the monitor was documenting one entry for the observation of 22 carcasses, whereas, according to the HACCP plan, entries were to be made for all the carcasses monitored. **b)** The establishment's HACCP plan did not include supportive documentation for the verification frequency to ensure that the monitoring was implemented effectively. [9 CFR 417.5(a)(3) and 417.17]

39/51/56. a) An accumulation of fat residue from the previous day's operations was observed on beams and pipes in the hog dehairing room. **b)** Several doors between the equipment washing room, processing rooms, and packaging rooms opened upwards, and wet floors below the doors presented a potential hazard for water dripping onto exposed edible product and employees' clothes while passing through these doors. [9 CFR 416.2(b) and 416/17 and C/D 64/433/EEC Annex 1 Chapter II(2)]

41/51/56. Beaded condensate was observed on overhead pipes and a rail in one carcass cooler. [9 CFR 416.2 (d) 416.17 & EEC C/D 64/433 of June 26, 1964. Annex1 Chapter1]

51. a) In establishment, Danish Veterinary Food Administration (DVFA) inspection officials were not verifying and documenting the adequacy of the establishment's procedures at a frequency sufficient to ensure that swine carcasses were not contaminated with fecal material, ingesta, or milk after the final rail inspection station. [9 CFR 310.17(a) and 310.18(a) and FSIS Directive 6420.2]

b) In establishment, DVFA inspection officials were not verifying corrective actions documented in the establishment's operational sanitation records, either to ensure appropriate disposition of products that could be contaminated or to prevent recurrence of direct product contamination or adulteration. [9 CFR 416.17]

c) In establishment, DVFA inspection officials were not verifying the adequacy and effectiveness of the SSOP at a frequency sufficient to ensure that the establishment met the FSIS requirements for reviewing the SSOP, daily records and any corrective actions taken and direct observation or testing to assess the sanitary conditions in the establishment. DVFA officials accompanied establishment personnel while the latter were conducting the pre-operational and operational procedures, (looking over the shoulder) and no deficiencies were observed by inspection officials. Records indicated that the inspection officials had conducted pre-operational and operational sanitation SSOP verifications one per month since January 2007. [9 CFR 416.17]

d) In establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements such as: Reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, and onsite observations and record review. Records indicated that inspection officials had conducted one direct observation at a CCP, one record review, and one calibration of process monitoring instrument review since January 2007. [9 CFR 417.8]

e) In establishment, DVFA inspection officials did not have adequate HACCP/ Pathogen Reduction trainings. [9 CFR 417.7]

51/57. Periodic supervisory reviews were routinely conducted by the District Veterinarian, but there was no indication of any findings concerning the aforementioned HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

58. Following a review of the findings by the FSIS, the establishment was issued a Notice of Intent to Delist (NOID). Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faiz R Choudry 5/23/07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agri-Norcold A/S Korsor, Denmark	05/02/07	4946	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	O
24. Labeling - Net Weights	O
25. General Labeling	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment 4946, Agri-Norcold, Korsor, Denmark; May 2, 2007 Cold storage

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R. Choudry 5/23/07

MINISTRY OF FAMILY
AND CONSUMER AFFAIRS
Danish Veterinary
and Food Administration

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

INTERNATIONAL TRADE DIVISION

att.: Karen Stuck

11 September 2007
File: 2007-20-7515-00092/HPE

Comments on Draft Final Report, Denmark, April 17 through May 11, 2007

Dear Karen Stuck.

The Danish Veterinary and Food Administration (DVFA) acknowledge the receipt of FSIS Draft Final Report of an audit carried out in Denmark covering Denmark's Meat Inspection System, April 17 through May 11, 2007. By letter of July 10, 2007 FSIS has invited DVFA within 60 days of the receipt of the Draft Report to provide comments regarding the information in the report.
DVFA hereby wish to state the following comments:

Page 4, Abbreviations:

"RVFCA - Regional Veterinary and Food Control Authority" should be corrected as follows:
"RVFAC - Regional Veterinary and Food Administration Centre"
Changes in the report should be made as a consequence of this correction.

"RVS – Regional Veterinary Supervisor" should be corrected as follows:
"RVS – Regional Veterinary Supervisor for the US certified establishments"

3.

Page 6:
Last paragraph concerning Salmonella testing. It is mentioned in the report that Denmark has the same requirement as FSIS for Salmonella testing with the following exeptions:
1st bullet: The establishments take the samples
5th bullet: NMKL method #71 and IQ Check method are used to analyze samples.
Comments: The samples taken by the establishments are verified by sampling carried out by the DVFA.
In addition to the NMKL and the IQ check methods the DVFA has by letters of 28 November 2002 and 22 December 2006 informed FSIS that the Vidas and EiaFoss Salmonella testing methods are used in Denmark. However, the EiaFoss method is not used any longer.

Mørkhøj Bygade 19
DK-2860 Søborg
T +45 33 95 60 00
F +45 33 95 60 01
www.fvst.dk
fvst@fvst.dk

6.1
2nd paragraph
Order number 282 of April 18, 2005 has been replaced by Order number 45 of January 18, 2007.

6.2.1
Last paragraph page 9 and 1st paragraph page 10:
"There are seven Divisions under the Danish Veterinary and Food Administration as follows: ....."
should be corrected as follows:
"There are twelve Divisions under the Danish Veterinary and Food Administration as follows: Animal Health Division, Control Coordination Division, International Trade Division, Division for Microbiological Food Safety, Hygiene and Zoonoses Control, Division for Chemical Food Safety, Animal Welfare and Veterinary Medical Products, Division for Food Quality, Technology and Marketing Practices, Division for Nutrition, Communication Division, Division for legal Affairs and International Coordination, Finance and Accounts Division, Human Resources Division, IT Division"

Page 10, 3rd paragraph, 1st line
The Audit Unit described in this paragraph is not the Audit Unit under ITD, but the External Audit Unit of DVFA, therefore
"The Audit Unit under ITD" should be changed to "The External Audit Unit of DVFA".
The responsibilities of the Audit Unit under ITD should be added as follows:
"The Audit Unit under ITD carries out central supervision of the regional DVFA personnel and is involved in periodic audits and approval of US certified establishments."

Page 10, 4th paragraph:
This paragraph should be corrected as follows:
"The responsibilities of the periodic supervisory reviews in the US certified establishments are shared as follows: The Regional Veterinary and Food Administration Centers (RVFAC) carries out monthly supervisory reviews in the US certified establishments. The Audit Unit under ITD carries out central supervision of the regional DVFA personnel (RVFAC) and is involved in periodic audits and approval of US certified establishments with the following frequencies: Four audits in slaughter establishments, three audits in processing establishments and two audits in cold stores per year."

Page 10, 5th paragraph,
In 5th line the word "supervision" should be changed to "supervision of the individual inspector".
Last sentence "Under the CCD there are three RVFCC (Region North, Region south, and Region East)." should be corrected as follows:
"The CCD undertakes an annual supervision of each Regional Veterinary and Food Admini-

stration Centre (RVFAC) to ensure uniformity, evaluate whether inspections are performed in a satisfactory manner and in accordance with procedures, and evaluate the management of the local Control and Enforcement Offices."

Page 10, 6th paragraph
"The regional veterinary and food control centers have a total of ten control and enforcement offices across the whole of Denmark" should be corrected as follows:
"DVFA has three Regional Veterinary and Food Administration Centers, RVFAC (Region North, Region South, and Region East). They have a total of ten Control and Enforcement Offices across the whole of Denmark."
The following sentence should be added:
"The Control and Enforcement Offices have a total of 16 District Veterinary Officers in charge of the inspection in slaughterhouses and other meat establishments."

Page 10, 7th paragraph
The paragraph should be corrected as follows:
"The Head of the Control and Enforcement Office is in charge of the supervision of the individual inspectors. However, the responsibility for the supervision of Official Veterinarians and non-veterinary technicians located at meat establishments has been delegated to the District Veterinary Officer.
The Head of the Control and Enforcement Office is responsible for the periodic (monthly) supervisory reviews at US certified meat establishments. Under his responsibility the supervisory reviews are carried out by Regional Veterinary Supervisors."

6.2.2, page 11
2nd paragraph, 3rd line:
"The head of the Import and Export Division of the Food Department" should be corrected as follows:
"The Head of the International Trade Division of the DVFA"

Page 11, 2nd paragraph
4th bullet: "DVAF" should be corrected to "DVFA"

6.2.3, page 11
1st paragraph, 6th line:
"The course consists of 14 weeks of theoretical training and seven weeks of practical training" should be corrected as follows:
"The course consists of 18 weeks of theoretical training and 15 weeks of practical training"

Page 12, 3rd paragraph:

"The RVFCA coordinator and the Head Veterinary Supervisor develop a yearly supervision plan..." should be corrected as follows:
"The RVS develops a yearly supervision plan..."

7, page 14
1st paragraph, 5th line:
"These seven establishments may retain their certifications for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishments were reviewed"
The following should be added:
"By letter of May 25, 2007 to FSIS the DVFA certified that all deficiencies noted during the audit had been corrected in the establishments that received a Notice of Intent to Delist.

13.1
3rd line:
"However, in processing establishments, second shift processing operations, and cold storages, the inspection coverage was provided periodically" should be corrected as follows:
"In processing establishments inspection was carried out daily on each shift when US destined products were produced. In US certified cold stores inspection was carried out weekly".

13.2
2. *Salmonella testing strategy:*
1st bullet, 2nd period:
"Denmark collects one sample per production day,..." should be corrected as follows:
"Each US certified slaughter establishment collects one sample per production day..."

Establishment audit reports

General remark:
51/57: "Periodic supervisory reviews were routinely conducted by the District Veterinarian" should be corrected as follows:
51/57: "Periodic supervisory reviews were routinely conducted by the RVS"

Establishment 318,
51 a, last period: "Records indicated that inspection officials had conducted only four pre-operational and two operational sanitation SSOP verifications since January 2007" should be corrected as follows:
"Records indicated that inspection officials had conducted five pre-operational and forty operational sanitation SSOP verifications since January 2007".

Establishment 338
10/51c:
"The hind legs of swine carcasses were contacting a black greasy rail and plastic protective coverings when they were entering the carcass cooler from the slaughter room"

The following should be added: "The hind legs were routinely condemned, and this had been verified by the DVFA officials"

Please do not hesitate to contact the International Trade Division (3.kontor@fvst.dk) if you need a clarification of the above comments.

Yours sincerely

Tina Lund Jensen
Head of International Trade Division (Acting)
DVFA