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

Dr. Birgitte Povlsen
Senior Veterinary Officer
Head of Import-Export Division
Food Department
Danish Veterinary and Food Administration
Moerkhoel Bygad 19
DK – 2860 Soeborg
Denmark

JAN 13 2006

Dear Dr. Povlsen:

The Food Safety and Inspection Service conducted an on-site audit of the Denmark meat inspection system June 29 through August 4, 2005. The comments from Denmark have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White

Sally White,
Director
International Equivalence Staff
International Affairs

Enclosure

cc:

Roger Wentzel, Agricultural Counselor, American Embassy, The Hague
Steen Thorsted, Minister Counselor, Royal Danish Embassy, Wash DC
Canice Nolan, Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the United States, Wash DC
Scott Bleggi, FAS Area Officer
Barbara Masters, Administrator, FSIS
Robert Macke, International Trade Policy, FAS
Linda Swacina, Executive Director, FSIA, OIA
Karen Stuck, Assistant Administrator, OIA, FSIS
William James, Deputy Assistant Administrator, OIA, FSIS
Amy Winton, State Department
Donald Smart, Director, OPEER, FSIS
Clark Danford, Director, IEPS, OIA
Sally White, Director, IES, OIA
Mary Stanley, Director, IID, OIA
Barbara McNiff, FSIS Codex Programs Staff, OIA
Jack Mowbray, IES, OIA
Country File

FINAL

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

JUNE 29 THROUGH AUGUST 4, 2005

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

CCA	Central Competent Authority (Danish Veterinary and Food Administration)
DVFA	Danish Veterinary and Food Administration
RVFCA	Regional Veterinary and Food Control Authority
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species

1. INTRODUCTION

The audit took place in Denmark from June 29 through August 4, 2005.

An opening meeting was held on June 29, 2005, 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 Audit Unit, a division within the Danish Veterinary and Food Administration (DVFA).

2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: The headquarters of the CCA, four regional inspection offices, three laboratories performing analytical testing on United States-destined product, four swine slaughter establishments, six meat processing establishments and three cold storage facilities.

Competent Authority Visit			Comments
	Central	1	
	Regional	4	
	Local	13	Establishment level
Laboratories		3	
Meat Slaughter Establishments		4	
Meat Processing Establishments		6	
Cold Storage Facilities		3	

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 13 establishments: four slaughter establishments, six processing establishments and three cold storage facilities. The fourth part involved visits to one private laboratory and two government laboratories. The private laboratory, located in Thisted, was conducting analysis of generic *E. coli* Biotype I samples and *Salmonella* carcass swab samples. The Regional Microbiology Laboratory, located in Ringsted was conducting analyses of field samples for the presence *Salmonella* and the Regional Residue Laboratory, located in Arhus was conducting analyses of field samples for Denmark's national residue control program.

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.

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.

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 following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted in January/February 2003:

Government Oversight

- Assignment of Inspectors: Deficiencies in inspection controls were identified in three establishments.
- Enforcement of U.S. Requirements: One establishment was delisted and two received a Notice of Intent to Delist.

Sanitation

- Four establishments had not adequately implemented their SSOP.
- Five establishments had not adequately documented deficiencies or corrective actions.
- Seven establishments had not met the requirements of EC Directive 64/433.
- Other sanitation deficiencies were documented in five establishments.

Slaughter/Processing

- Three establishments had not fully implemented their HACCP plans.

- Testing for generic *E coli*: In one establishment, statistical process control to evaluate the results of testing for generic *E. coli* had not been properly implemented and documented.

- Ante-mortem and post-mortem inspection: Unified synchronization of inspected carcasses needs improvement in one establishment.

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 records documenting pre-operational sanitation noncompliances for product contact equipment.

- Non-compliances were not sufficiently documented to demonstrate the monitoring of the SSOP in the daily pre-operational sanitation records.

- On-going verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed.

- On-going verification activities for the review of records generated and maintained was not performed.

- The establishment had not included in their HACCP plan corrective actions identifying the cause and elimination of a deviation and had not established 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:

Government Oversight

- FSIS requirements were not enforced in nine establishments.

- The FSIS auditor recommended a Notice of Intent to Delist be issued to two establishments.

- Some general audit finding identified during the January/February audit of 2003 were also identified during the September 2004 audit. Examples of general repeat findings:

    - 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.

Sanitation

- 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.

EC Directive 64/433

- 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.

Slaughter/Processing

- Nine establishments failed to implement their HACCP plans.

- One establishment did not meet FSIS requirements for the production of Read-to-Eat products for export to the United States.

Enforcement Controls

- 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.

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 Denmark's legislation, allowing 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, was officially enacted May 1, 2005.

6.2 Government Oversight

6.2.1 CCA Control Systems

The Danish Veterinary and Food Administration (DVFA) notified the auditor that there have been no major changes in the administrative structure of the DVFA.

The DVFA is considered the CCA and is comparable to the Food Safety Inspection Service (FSIS) in the United States. Administration, development, coordination and the formation of rules and regulation take place in the headquarters of the DVFA in Copenhagen and are organized in three units: The Food Department, the Veterinary Service Department and the Administrative Department.

The Food Department is divided into five divisions: The Division of Control Coordination, Division of Food Safety, Division of Nutrition, Division of Organic Food, Marketing and Food Technology and Division of Internal Control, Import, Export and the Audit Unit. The Division of Internal Control, Import, Export and Audit Unit is responsible for rules on internal control, rules concerning national and international inspection procedures, rules on authorization, approval and registration of food enterprises, management of the control of food imports and exports, management of the control of food stuffs trade, planning and organizing inspection visits and international inspection procedures, civil contingency capabilities, serving as a contact point for the Rapid Alert System and the Audit Unit.

The Audit Unit was established January 1, 2004 and conducts regular audits of Denmark's meat inspection system and FSIS requirements in United States certified establishments. The intent of the Audit Unit is to perform quarterly audits of the inspection system in each establishment certified to export to the United States.

Food control and veterinary inspection responsibilities are managed from 10 Regional Veterinary and Food Control Authorities (RVFCA). Each RVFCA contains a Food Department, a Veterinary Department and an Administration Department. Six of the 10 RVFCA contain laboratories for the testing of food products.

Within each RVFCA was the Head of the Regional Food Department, in-charge of all supervision activities and the Head Veterinarians, who served as field supervisors over the official veterinarians located at the establishment level. Non-veterinary technicians assigned to either slaughter or processing establishments are supervised by either the head veterinarian or the official veterinarian.

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 RVFCA, the DVFA develops and distributes official legislation to the RVFCA. The DVFA coordinates the implementation of inspection activities at each RVFCA 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 RVFCA 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 Import and Export division of the Food Department is responsible for the official certification or decertification of U.S. establishments and is responsible for maintaining the official list of establishments eligible to export to the United States.

6.2.3 Assignment of Competent, Qualified Inspectors

The RVFCA is responsible for the initial hiring, training and payment of veterinarians and non-veterinary technicians. Veterinarians receive class room 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 14 weeks of theoretical training and seven weeks of practical training. On-going training needs are determined and scheduled by the official veterinarian or the head veterinarian through consultation with the RVFCA. 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 RVFCA. This is required by an official contract between the RVFCA and the DVFA.

The RVFCA coordinator and Head Veterinary Officers develop 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.

6.2.4 Authority and Responsibility to Enforce the Laws

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

- FSIS requirements were not completely enforced in seven establishments.
- The DVFA recommended a Notice of Intent to Delist be issued to one establishment.

- Some general audit findings identified during the September audit of 2004 were also identified during the current June 29 through August 4, 2005 audit. Examples of general repeat audit findings:

    - The establishment did not follow written procedures in their pre-operational and operational SSOP by failing to fully describe sanitation deficiencies, proper disposition of contaminated product, restore sanitary conditions and prevent recurrence of contamination of direct product contact surfaces.

    - The hazard analysis did not include all hazards reasonably likely to occur. Stabilization, for the chilling of cooked pork, was not included in the flow chart as a processing step and was not identified as a food safety hazard reasonably likely to occur for this processing step.

    - On-going verification activities for the direct observation of the monitoring of critical limits for critical control points and corrective actions were not performed.

    - On-going verification activities for the review of records generated and maintained was not performed.

    - The establishment employee making entries on the calibration of thermometers record failed to initial the document.

    - 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 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.

6.2.5 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 RVFCA located in Haderslev, Ringsted, Vejle and Viborg 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 13 establishments. Four were slaughter establishments, six were processing establishments and three were cold storage facilities. No establishments were delisted by Denmark. One establishment received a Notice of Intent to Delist (NOID) from the DVFA because the establishment failed to implement their SSOP and HACCP plans. This establishment may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was 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 Microbiology Laboratory, located in Ringsted, one Regional Residue Laboratory, located in Arhus and one Private Microbiology Laboratory, located in Thisted.

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 SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or 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 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:

- 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 intestines and spleen, at the evisceration stand, were removed from one carcass and dropped onto the eviscerator's boot. The boot was not cleaned and sanitized between each evisceration process and the evisceration stand was not a sanitary surface.

    - 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.

- The written procedure, describe in the SSOP for meat dropped onto the floor, was not followed.

- 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.

9.2 EC Directive 64/433

In nine establishments, the provisions of EC Directive 64/433 were effectively implemented. In the four establishments with deficiencies, the specific deficiencies are noted in this section and other applicable sections and sub-sections of this report and in the attached individual establishment reports.

- Four 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. 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.

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, reconditioned product and the implementation of the requirements for the control of Bovine Spongiform Encephalopathy. The auditor determined that Denmark's inspection system had adequate controls in place. No deficiencies were noted.

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

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, dried, and cooked products.

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

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

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

Three establishments audited were cold storage facilities that conducted freezing and storage of boxed pork products for export to the United States and were not required to have developed a HACCP program.

The HACCP programs were reviewed during the on-site audit of ten establishments. Although the HACCP plans in the 10 establishments were found to meet the basic FSIS regulatory requirements, it was found that five of the 10 establishments had not adequately implemented their HACCP plans. Examples of these deficiencies include:

- In two establishments the HACCP plan did not include all required components.

- Stabilization, for the chilling of cooked pork, was not included in the flow chart as a processing step and was not identified as a food safety hazard reasonably likely to occur for this processing step.

- Monitoring of the critical limit for temperature was performed, but procedures for monitoring were not clearly described in the HACCP plan or in monitoring procedures. The critical limit for temperature was monitored by an electronic computer system, but the results were not clear on the printed form.

- One establishment did not verify that the HACCP plan was being effectively implemented. For example:

  - On-going verification activities for the direct observation of the monitoring of critical limits for critical control points and corrective actions were not performed.

  - On-going verification activities for the review of records generated and maintained were not performed.

- Four establishments did not maintain records that document their HACCP plan. For example:

  - Monitoring results for the measurement of the critical limit for zero-tolerance for fecal contamination, and the critical limit for temperature of casings prior to shipping were transferred to another record, but the original record with the actual time the results were recorded was not attached to the new record.

  - The monitor for the measurement of the critical limit for zero-tolerance for fecal contamination recorded results three times during the production shift, but the record was only initialed once.

  - Monitoring results for the measurement of the critical limit for room temperature in the chilling room for carcass were not linked to the electronic records used to record the actual critical limit.

  - The establishment employee making entries on the calibration of thermometers record failed to initial the document.

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*.

Denmark has submitted the use of an approved NMKL method as the equivalent method to be used to analyze samples for generic *E. coli*. The U.S. AOAC 991.14 Petrifilm method for the analysis of generic *E. coli* samples is also used.

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

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

11.4 Testing for *Listeria monocytogenes*

Two establishments were producing ready-to-eat products eligible for export to the United States. The two establishments met FSIS *Listeria* requirements.

11.5 EC Directive 64/433

The provisions of EC Directive 64/433 were 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 Arhus was audited. No deficiencies were noted.

Denmark's National Residue Control Program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In the Regional Veterinary Food Control Authority Residue Laboratory, located in Arhus, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the Regional Veterinary Food Control Authority Residue Laboratory, located in Arhus, the provisions of EC Directive 96/23 were effectively implemented.

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

Daily inspection was provided as required for all establishments audited; however, in one establishment, inspection coverage was not routinely provided during the second shift. FSIS is working with DVFA to resolve this issue.

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 one of the six Regional Veterinary Food Control Authority Microbiology Laboratories.

2. Private laboratories located in selected establishments analyze *Salmonella* Performance Standards samples.

- Test results are provided directly to the government veterinarian.

3. *Salmonella* testing strategy

- The DVFA uses a continuous, ongoing sampling program. Denmark 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.

4. A gauze pad sampling tool is used.

Four 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 of the four slaughter establishments audited.

13.3 Verification Testing Program for Ready-to-Eat Product

One establishment audited was exporting Ready-to-Eat product to the United States. Verification testing for *Listeria monocytogenes* and *Salmonella* was conducted as required.

13.4 Species Verification

Species verification testing was being conducted in 13 of the 13 establishments audited.

13.5 Monthly Reviews

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

13.6 Enforcement of FSIS Requirements

FSIS requirements were not enforced in seven establishments. For example:

- The DVFA recommended a Notice of Intent to Delist be issued to one establishment.

- The written procedure, described in the SSOP for meat dropped onto the floor, was not followed.

- 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 establishment did not follow written procedures in their pre-operational and operational SSOP by failing to fully describe sanitation deficiencies, proper disposition of contaminated product, restore sanitary conditions and prevent recurrence of contamination of direct product contact surfaces. 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.

- On-going verification activities for the direct observation of the monitoring of critical limits for critical control points and corrective actions were not performed.

- On-going verification activities for the review of records generated and maintained were not performed in one establishment.

- Stabilization, for the chilling of cooked pork, was not included in the flow chart as a processing step and was not identified as a food safety hazard reasonably likely to occur for this processing step.

- Monitoring results for the measurement of the critical limit for zero-tolerance for fecal contamination, and the critical limit for temperature of casings prior to shipping were transferred to another record, but the original record with the actual time the results were recorded was not attached to the new record.

- The monitor for the measurement of the critical limit for zero-tolerance for fecal contamination recorded results three times during the production shift, but the record was only initialed once.

- Monitoring results for the measurement of the critical limit for room temperature in the chilling room for carcass were not linked to the electronic records used to record the actual critical limit.

- A production worker deboning pork cuts was instructed by the production manager to pick up product dropped onto the floor. The production worker placed the dropped product onto a reconditioning table and proceeded to his work station without washing his hands.

- Verification of Pre-operational sanitation is schedule to be performed six times per year by the Viborg Regional Office in the nine establishments, within the region, certified to export meat products to the United States. Review of DVFA inspection records indicated that verification of pre-operational sanitation had been performed one time from January 1, 2005 to July 22, 2005. The results of audit findings recorded under checklist item number 10, implementation of the establishment's SSOP, substantiates the fact that the frequency of the DVFA's verification of pre-operational sanitation was not performed at a frequency adequate to verify the implementation of pre-operational cleaning.

- 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.

13.7 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.

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

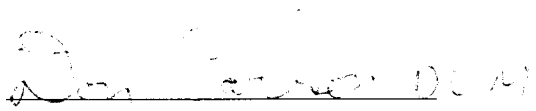
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on August 4, 2005, 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.

Don Carlson, 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 Tulip Food Company Ringsted, Denmark	07/04&05/05	25	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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	
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	
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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

07/04 &05/05: Est. 25, Danish Crown, Slaughter, Deboning, Further Processing, RTE, Ringsted, Denmark

10/51. The establishment failed to follow written procedures described in their SSOP and did not implement their SSOP for meat dropped onto the floor. Meat dropped onto the floor of deboning room number 4, was placed onto the surface of a reconditioning table with out applying a clean sheet of plastic on the surface of the table before each use. The shift started production at 6:30 am. The observation was made at approximately 9:00 am. The surface of the table was completely covered with blood and meat residue. The establishment supervisor of the area, when interviewed, stated the written meat reconditioning procedures had not been followed. [Reference: 9CFR 416.13 (c) and 416.17]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/05/05

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, Tulip Holbæk, Denmark	07/06/2005	30	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs 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	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

07/06/2005: Est. 30, Danish Crown, Tulip, Deboning, Holbæk, Denmark

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
Dr. Don Carlosn	Dr. Don Carlson /s/ 07/06/2005

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 Skive, Denmark	07/19/2005	47	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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 SSOPs 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.	X
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	
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	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	X
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	
58.	
59.	

60. Observation of the Establishment

07/19/2005: Est. 47, Danish Crown, Slaughter, Cutting, Deboning and Salt Nitrite injection, Skive, Denmark

10/51. 1. An establishment employee, eviscerating swine 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 establishment and DVFA auditor took immediate and appropriate corrective actions. [Reference: 9CFR 416.13 (c) and 416.17]

10. 2. The intestines and spleen, at the evisceration stand, were removed from one carcass and dropped onto the eviscerator's boot. The boot was not cleaned and sanitized between each evisceration process and the evisceration stand was not a sanitary surface. The establishment and DVFA auditor took immediate and appropriate corrective actions. [9CFR 416.13 (c)]

15/51. The hazard analysis did not include all hazards reasonably likely to occur. Stabilization, for the chilling of cooked pork, was not included in the flow chart as a processing step and was not identified as a food safety hazard reasonably likely to occur for this processing step. The establishment was not currently producing cooked pork and had not produced this product since March of 2005. [9CFR 417.2 (a) (2) and (c) (1)] [9CFR 417.8]

22/51. Monitoring results for the measurement of the critical limit for zero-tolerance for fecal contamination were transferred to another record, but the original record with the actual time the results were recorded was not attached to the new record. [9CFR 417.5 (3) (b) and 417.8]

47/51/56. Establishment employees and DVFA inspection officials working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. Establishment employees changed into work uniforms, hair nets, head coverings and proceeded to walk out side and smoke cigarettes, carry personal items and spend time in conversation out side of the establishment. Establishment employees walked freely to various production buildings located on the official premise. The production buildings were located approximately 50 to 200 yards apart. 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. [9CFR 416.5 (b) and 416.17] [EC Directive 64/433]

50. Direct and continuous official supervision of preparation of product, by the assignment of inspectors to the 10:40 pm to 6:00 am salting and packaging shift, to assure that adulterated or misbranded product is not prepared for export to the United States was not provided by the DVFA. The DVFA provided inspection for this shift approximately one time per month. [9CFR 327.2 (a) (2) (ii) (D)]

.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/19/2005

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 Esbjerg, Denmark	07/14/2005	53	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs 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.	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	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
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	
58.	
59.	

60. Observation of the Establishment

07/14/2005: Est.53, Danish Crown, Slaughter and Deboning, Esbjerg, Denmark

22/51. Monitoring results for the measurement of the critical limit for zero-tolerance for fecal contamination, and the critical limit for temperature of casings prior to shipping were transferred to another record, but the original record with the actual time the results were recorded was not attached to the new record. The monitor for the measurement of the critical limit for zero-tolerance for fecal contamination recorded results three times during the production shift, but the record was only initialed once. [Reference: 9CFR 417.5 (3) (b) and 417.8]

47/51/56. 1. Establishment employees and DVFA inspection officials working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. Establishment employees changed into work uniforms, hair nets, head coverings and proceeded to walk out side and smoke cigarettes, carry personal items and spend time in conversation out side of the establishment. Establishment employees walked freely to various production buildings located on the official premise. The production buildings were located approximately 50 to 200 yards apart. 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. [9CFR 416.5 (b) and 416.17] [EC Directive 64/433]

2. A production worker deboning pork cuts was instructed by the production manager to pick up product dropped onto the floor. The production worker placed the dropped product onto a reconditioning table and proceeded to his work station without washing his hands. The production worker's insanitary action was not identified by the establishment or by DVFA inspection officials. The production worker was directed to wash his hands by the production manager. No product was adulterated. [9CFR 416.5 (a) and 416.17] [EC Directive 64/433]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/14/2005

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	07/15/2005	60	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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

07/15/2005: Est. 60, Danish Crown, Cold Storage, Holstebro, Denmark

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
Dr. Don Carlson	Dr. Don Carlson /s/ 07/15/2005

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
Sydfrost, Claus Sørensen A/S Padborg, Denmark	07/12/2005	101	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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

07/12/2005: Est. 101, Sydfrost, Cold Storage, Padborg, Denmark

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
Dr. Don Carlson	Dr. Don Carlson /s/ 07/12/2005

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 Nykøbing, Denmark	07/26/2005	172	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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

07/26/2005: Est. 172, Agri-Norcold A/S, Cold Storage, Nykøbing, Denmark

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
Dr. Don Carlson	Dr. Don Carlson /s/ 07/26/2005

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
Claus Sørensen A/S Vejle, Denmark	07/08/2005	189	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
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.	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	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

07/08/2005: Est. 189, Claus Sørensen A/S, Deboning, Cold Storage, Vejle, Denmark

22. The establishment employee making entries on the calibration of thermometers record failed to initial the document. Thermometers were calibrated one time per year and within the last thirty days; the establishment increased the frequency to two times per year. [Reference: 9CFR 417.5 (3) (b)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/08/2005

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
Tulip Food Company Svenstrup, Denmark	07/27/2005	211	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
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	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

07/27/2005: Est. 211, Tulip Food Company, Svenstrup, RTE further processing, Denmark

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
Dr. Don Carlson	Dr. Don Carlson /s/ 07/27/2005

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
Scanflavour A/S Møldrup Denmark	07/20/2005	215	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs 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	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

0720/2005: Est. 215, Scanflavour A/S, Processing, Dried Protein, Møldrup, Denmark

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
Dr. Don Carlson	Dr. Don Carlson /s/ 07/20/2005

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 Rødding, Denmark	07/13/2005	318	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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 SSOPs 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.	X
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.	X
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	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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	X
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	
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment

07/13/2005: Est. 318, Danish Crown, Deboning, Rødding, Denmark

10/13/51. 1. The establishment did not follow written procedures in their pre-operational and operational SSOP by failing to fully describe sanitation deficiencies, proper disposition of contaminated product, restore sanitary conditions and prevent recurrence of contamination of direct product contact surfaces. [Reference: 9CFR 416.13 (c), 416.16 and 416.17]

2. 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. The DVFA inspector identified meat and fat particles, meat and fat residue, black grease and rust on approximately 20 product contact and non-product contact surfaces, in the deboning room, during verification of pre-operational sanitation that the establishment failed to identify on their pre-operational sanitation report. Product contact surfaces included equipment, product belts and cutting boards. The surface of the majority of cutting boards were scared with deep knife cuts and in poor condition. Non-product contact surfaces included equipment handles, electronic touch screens, framework for product conveyors, walls and over product structures. The DVFA inspector and the establishment took immediate and appropriate corrective actions; however many of the deficiencies identified by the DVFA inspector were of a long standing nature and should have been identified prior to this pre-operational verification inspection. [9CFR 416.13 (c), 416.16 and 416.17]

15/51. Monitoring of the critical limit for temperature was performed, but procedures for monitoring were not clearly described in the HACCP plan or in monitoring procedures. The critical limit for temperature was monitored by an electronic computer system, but the results were not clear on the printed form. [9CFR 417.2 (c) (4) and 417.8]

19/51. 1. Ongoing verification activities for the direct observation of the monitoring of critical limits for critical control points and corrective actions were not performed. [Reference: 9CFR 417.4 (a) (2) (ii) and 417.8]
2. Ongoing verification activities for the review of records generated and maintained were not performed. [9CFR 417.4 (a) (2) (iii) and 417.8]

41/46/51/56. 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. [9CFR 416.2 (d), 416.4 (b) and 416.17] [EC Directive 64/433]

47/51/56. 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 outside the establishment and then returning to production areas inside the establishment without changing work uniforms. Establishment employees changed into work uniforms, hair nets, head coverings and proceeded to walk out side and smoke cigarettes, carry personal items and spend time in conversation out side of the establishment. Establishment employees walked freely with in a 50 yard by 50 yard area. 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. [9CFR 416.5 (b) and 416.17] [EC Directive 64/433]

50. Direct and continuous official supervision of preparation of product, by the assignment of inspectors to the 3:15 pm to 11:00 pm shift, to assure that adulterated or misbranded product is not prepared for export to the United States was not provided by the DVFA. The shift produced pork products for approximately five weeks in 2005. The shift stopped operations in March of 2005 and is not currently operating. The DVFA provided assurances that when the shift resumes operations, daily inspection will be provided. [9CFR 327.2 (a) (2) (ii) (D)]

58. The Danish Veterinary and Food Administration issued to the establishment a Notice of Intent to Delist (NOID) for failure to implement their SSOP and HACCP plan.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/13/2005

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	07/22/2005	338	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	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	
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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

07/22/2005: Est. 338, TiCan A.m.b.A., Slaughter, Deboning, Thisted, Denmark

10. The DVFA veterinary inspector performing pre-operational sanitation verification inspection in the slaughter area, identified meat and fat particles, meat and fat residue, black grease and rust on approximately 20 product contact and non-product contact surfaces that the establishment failed to identify on their pre-operational sanitation report. Product contact areas included equipment, viscera pans and hooks used for lungs, livers and kidneys. Non-product contact surfaces included floors, walls and over product structures. The DVFA veterinary inspector issued a control action and slaughter operations were delayed approximately three hours. The slaughter area was reinspected by the DVFA veterinary inspector prior to the start of slaughter operations. [Reference: 9CFR 416.13 (c)]

22/51. 1. The monitor for zero-tolerance recorded results three times during the production shift, but the record was only initialed once. [9CFR 417.5 (3) (b) and 417.8]
2. Monitoring results for the measurement of the critical limit for room temperature in the chilling room for carcass were not linked to the electronic records used to record the actual critical limit. [9CFR 417.5 (3) (b) and 417.8]

51. Verification of Pre-operational sanitation is schedule to be performed six times per year by the Viborg Regional Office in the nine establishments, within the region, certified to export meat products to the United States. Review of DVFA inspection records indicated that verification of pre-operational sanitation had been performed one time from January 1, 2005 to July 22, 2005. The results of audit findings recorded under checklist item number 10, implementation of the establishment's SSOP, substantiates the fact that the frequency of verification of pre-operational sanitation was not performed at a frequency adequate to verify the implementation of pre-operational cleaning. [9CFR 416.17]

61. NAME OF AUDITOR	Dr Don Carlson	62. AUDITOR SIGNATURE AND DATE	Dr. Don Carlson /s/ 07/22/2005

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 Hurup, Denmark	07/25/2005	339	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	
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	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	X
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	
58.	
59.	

60. Observation of the Establishment

07/25/2005: Est. 339, Danish Crown, Deboning, Hurup, Denmark

47/51/56. 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 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. [9CFR 416.5 (b) and 416.17] [EC Directive 64/433]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Don Carlson	Dr. Don Carlson /s/ 07/25/2005

MINISTRY OF FAMILY
AND CONSUMER AFFAIRS
Danish Veterinary
and Food Administration

INTERNATIONAL TRADE DIVISION

United States Department of Agriculture
Food Safety and Inspection Service
Washington D.C.
20250
att. : Sally White, Director
International Equivalence Staff
Office of International Affairs

29.11.2005
File: 2005-20-7515-00079/HPE

Comments on draft audit report.

This is in response to letter from FSIS of September 22, 2005, received 4 October 2005, enclosed the draft audit report for the on-site audit of Denmark's meat inspection system, conducted June 29 through August 4, 2005.

By the letter Denmark was invited to provide comments regarding the information in the report within 60 days of the receipt of the letter. The Danish Veterinary and Food Administration hereby wish to forward the following comments:

1. Re: page 12, 6.2.4.
Repeated audit findings concerning wearing of work uniforms outside the establishment.

It is the viewpoint of the DVFA, that, with regard to the issue of employees and inspection personnel wearing working clothes outside the establishment (but within the premises) and then returning to production areas inside the establishment without changing working clothes, there is no specific provision in the EC Directive against this practice.

It is the view of the Danish Veterinary and Food Administration that if employees and inspection personnel leave the production area and walk outside during breaks, this does not necessarily mean that the working clothes get unclean and needs to be renewed immediately hereafter.

The establishments must have procedures in place to change working clothes, if they get unclean whether it is outside or inside the establishment.

The DVFA presented these viewpoints to the FSIS auditor.

Mørkhøj Bygade 19
DK-2860 Søborg

T +45 33 95 60 00
F +45 33 95 60 01

www.fvst.dk
fvst@fvst.dk

2. Re: page 13, 7.
One establishment received a Notice of Intent to Delist (NOID):

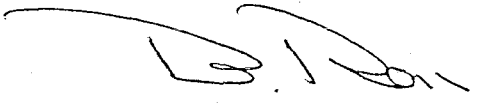
Follow- up report describing the corrective actions at the establishment has been forwarded to FSIS on September 21, 2005. The FSIS has responded by letter of October 7, 2005, that FSIS has lifted increased U.S. port-of-entry testing levels for this establishment.

3. **Re: page 18, 11.3**
Testing for Generic E. Coli. Notification of the use of the U.S. AOAC 991.14 Petrifilm method.
The use of the U.S. AOAC 991.14 Petrifilm method was notified to FSIS in letter from DVFA of March 1, 2005, comprising the DVFA´s remarks on the September 2004 FSIS audit report.

4. **Page 19, 13.1**
In one establishment daily inspection coverage was not routinely provided during the second shift.

By letter of July 21, 2005, FSIS has informed that inspection presence is required for all shifts (day and night) in which product is being produced for export to the U.S.
This requirement has been passed on to the Regional Veterinary and Food Control Authorities on September 5, 2005.

Yours faithfully



Birgitte Povlsen
Senior Veterinary Officer
Head of International Trade Division