United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

JUL 1 2008

Dr. Jan Mousing
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
Denmark

Dear Dr. Mousing:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Denmark's meat inspection system January 29 to March 11, 2008. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 690-5646, by facsimile at (202) 720-0676, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

/Donald C. Smart/

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

Steve Huete, Agricultural Attaché, American Embassy, The Hague
Anders Klôcker, Minister Counselor, Royal Danish Embassy
Bernard Van Goethem, Acting Director, Directorate E, European Commission, Brussels
Canice Nolan, First Secretary, EU Mission to the United States, Wash DC
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Denmark Country File

FSIS:OIA:IAS:DSMART:202-690-5646:06/30/08:Denmark Audit Final Report Letter June 30, 2008

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

JANUARY 29 THROUGH MARCH 11, 2008

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Danish Veterinary and Food Administration)
CCD	Control Coordination Division
CL	Critical Limit
DVFA	Danish Veterinary and Food Administration
DVO	District Veterinary Officer
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
ITD	International Trade Division
MFAF	Ministry of Food, Agriculture and Fisheries
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-To-Eat
RVFAC	Regional Veterinary and Food Administration Center
RVS	Regional Veterinary Supervisor
Salmonella	*Salmonella* Species
SPS	Sanitation Performance System
VEA	European Community/United States Veterinary Equivalence Agreement
WTO	World Trade Organization

1. INTRODUCTION

The audit took place in Denmark from January 29 through March 11, 2008.

An opening meeting was held on January 29 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 Audit Unit, International Trade Division (ITD), a division within the Danish Veterinary and Food Administration (DVFA).

2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: the headquarters of the CCA; one regional inspection office; 11 swine slaughter and meat processing establishments; two meat processing establishments; one laboratory conducting microbiological testing on U.S.-destined product; and one laboratory performing analytical testing for the National Residue Testing Program.

Competent Authority Visit			Comments
	Central	1	
	Regional	1	East Region in Ringsted
	Local	13	Establishment-level
Laboratories		2	
Slaughter and Meat Processing Establishments		11	
Meat Processing Establishment		2	

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: 11 swine slaughter and meat processing establishments and two meat processing establishments. The fourth part involved audits of two government laboratories: one Regional Veterinary and Food Administration Center (RVFAC) laboratory located in Aalborg that conducts microbiology samples for *Salmonella* species *(Salmonella)* testing, and another RVFAC laboratory located in Aarhus that conducts residue analytical testing of field samples for the National Residue Testing 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 (SSOP); (2) animal disease controls; (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs and a testing program for generic *Escherichia coli (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 that the production of meat products 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 Food Safety and Inspection Service (FSIS) auditor would audit the meat inspection system against European Commission (EC) Directive 64/433/EEC of June 1964; EC Directive 96/22/EC of April 1996; and EC 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; handling and disposal of inedible and condemned materials; species verification testing; requirements for HACCP and SSOP; and 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 the 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; and
- Use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* testing.

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

- The establishments take the samples;
- Private laboratories analyze the samples;
- A continuous, ongoing sampling program is used;
- A gauze pad sampling tool is used; and
- NMKL method #71and iQ Check method are used to analyze samples.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations; in particular:

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

In addition, compliance with the following EC 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"; and
- 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 the FSIS website at the following address:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

There was no audit in 2006.

The last FSIS audit of Denmark's meat inspection system was conducted April-May 2007.

The following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted April 17 through May 11, 2007:

- In seven of the eight establishments audited, establishment officials were not routinely evaluating the adequacy and effectiveness of the SSOP to prevent direct product contamination or adulteration;
- In seven establishments, pre-operational and operational SSOP implementation deficiencies were found;
- Product residues, pieces of fat and detergent residue from the previous day's operation were observed on food contact surfaces of plastic conveyor belts and carcass splitting saws in the primal cut-up room;
- Pieces of fat from the previous day's operations were observed on food contact surfaces in a packaging machine;
- Product residues from the previous day's operations were observed on food contact surfaces in the swine slaughter room, i.e., de-hairing equipment, a plastic conveyor belt,

a carcass splitting saw, a shovel for handling edible product, sanitizers, and employees' metal mesh gloves;

- Fat residues from the previous day's operations were observed on food contact surfaces in the cooler;
- Pieces of fat and detergent residues were observed in metal bins, ready for use, in the edible fat melting and boning rooms;
- Condensate was dripping onto tree hooks from an overhead pipe, electrical cables, and a rail in the equipment washing room. The hooks had been cleaned and sanitized and were ready to be used for edible product;
- Condensate was dripping from an overhead pipe onto hog carcasses at the entrance to the cooler;
- Pieces of fat and blood were observed on viscera pans, ready for use, in the slaughter room;
- The forelegs of swine carcasses were contacting the working platforms and employees' boots at the eviscerating stations in the slaughter room;
- Product residues and fat were observed on employees' metal mesh gloves, ready for use, in the cut-up room;
- Edible product was contacting non-food contact surfaces, e.g., a conveyor belt in the cut-up room;
- Fat, blood, and grease were observed on offal hooks, ready for use, in the slaughter room;
- Water from a sanitizer was falling onto the forelegs of carcasses during sanitization of equipment at the carcass eviscerating station in the slaughter room;
- In six establishments, deficiencies identified during pre-operational and operational verification of the SSOP were not adequately described on the records and did not document the corrective actions properly to prevent recurrence of direct product contamination or adulteration;
- Water was splashing from the floor onto the inverted food contact surfaces of the viscera pan conveyor in the slaughter room;
- In seven of the eight establishments audited, Sanitation Performance Standards (SPS) and EC Directive 64/433 requirements were not met; for example:

    - An accumulation of fat residue from the previous day's operations was observed on beams and pipes in the swine de-hairing room; and
    - Several doors between the equipment washing room, processing rooms, and packaging rooms opened upward, and wet floors below the doors presented a potential for water dripping onto exposed edible product and employees' clothes while passing through these doors.

- Seven of the eight establishments audited did not meet the requirements of SPS and EC Directive 64/433 and were not operating nor being maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product was not adulterated; for example:

    - Wet loose plastic was observed on the upper panel window through which the clean bins were passing through after washing and sanitizing;

- An accumulation of fat residue and black grease from the previous day's operations was observed on supports, beams, and the inner side of the plastic protective coverings on both sides of a rail in the swine de-hairing room;
- Flaking paint was observed on a wall behind the refrigeration unit in the offal cooler;
- An opening in the outside wall of the pallet storage room was not sealed properly to prevent the entry of insects, rodents, and other vermin.
- Several outside doors in the establishment were not sealed properly to prevent the entry of insects, rodents and other vermin.

- In two establishments, packaging supplies were kept in the dry storage room in a manner that prevented the inspection of the room for the presence of pests or insanitary conditions; for example:

    - Storage racks were not high enough and were stored against the walls or directly on the floor. Dead insects, dirt, and cobwebs were also observed in the room. Numerous pieces of used equipment and other non-packaging materials were stored directly on the floor. Open spaces at the bottom of a wall were not sealed properly to prevent the entry of insects, rodents, and other vermin.

- In four establishments, beaded condensate was observed on overhead pipes, rails, refrigeration units, and ducts in the coolers;
- In two establishments, the potable water storage tanks were not sealed properly to prevent entry of vermin and dust. Dead insects, cobwebs, rust, and an accumulation of dirt were observed inside the water tank lid;
- In one establishment, due to inadequate floor drainage at the container washing machine, water on the floor was falling onto containers waiting for cleaning in the room below;
- In one establishment, due to inadequate floor drainage, water had accumulated in the swine brisket-opening cabinet;
- In one establishment, edible and inedible product containers, ready for use, were commingled in a container storage room.
- In another establishment, edible offal and pet food bins were commingled in the cooler;
- In two establishments, product was not adequately protected from adulteration during processing, storing, and transporting; for example:

    - Edible product was not properly protected from any fallout from the overhead catwalk in the edible fat room;
    - The bottom of plastic strip curtains was contacting employees' boots and clean clothes, edible product containers, and exposed edible products when they were passing through the doors of the production room;
    - An accumulation of fat residue from the previous day's operations was observed inside of the exhaust system of a washing machine and rusty drying equipment was noticed over the container cleaning line in the washing room; and

- Fat residue was observed inside a cabinet for drying viscera pans in the slaughter room.

- In one establishment, an employee was observed picking up pieces of meat from non-food contact surfaces, saving them in a container for edible product and, without washing his hands, handling edible product in the packaging room;
- In six of the seven establishments, one or more HACCP problems (implementation) were observed; for example:

    - In two establishments, monitoring procedures were not described adequately for the Critical Control Points (CCPs) to ensure compliance with the Critical Limit (CL) in the HACCP plan.

- In one establishment, monitoring procedures were not conducted as specified in the HACCP plan for the second-shift operation;
- In two establishments, when deviations from CLs occurred, establishment employees failed to take corrective actions; there were no records that documented that:

    - The cause of the deviation was eliminated;
    - The CCP was brought under control after corrective action was taken;
    - Measures to prevent recurrence were established; and that
    - No product that was adulterated as a result of the deviation entered commerce.

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

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

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

- The periodic supervisory reviews that were conducted for seven of the eight establishments audited did not reflect actual establishment conditions; and
- It appeared that the formal training in PR/HACCP systems was not sufficient to ensure enforcement of U.S. requirements.

FSIS requirements were not adequately enforced; for example:

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

6. MAIN FINDINGS

6.1 Legislation

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

The auditor was informed that relevant FSIS regulations had been transposed into Danish legislation. This allows legal sanctions to be issued to establishments that do not comply with third-country export requirements. The specific legislation is Danish Order Number 1282, November 6, 2007.

6.2 Government Oversight

6.2.1 CCA Control Systems

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

- The Danish Veterinary and Food Administration (DVFA) is the Central Competent Authority (CCA) under the Ministry of Food, Agriculture, and Fisheries (MFAF) in Copenhagen;
- Three Regional Veterinary and Food Administration Centers (RVFAC) located in the North, South, and East;
- DVFA, Region North, with its head office in Århus, has four control and enforcement offices in Ålborg, Herning, Viborg and Århus;
- DVFA, Region South, with its head office in Vejle, has four control and enforcement offices in Vejle, Esbjerg, Haderslev and Odense; and
- DVFA, Region East, with its head office in Ringsted, has two control and enforcement offices in Rødovre and Ringsted and a local office in Rønne.

Inspection at meat and food establishments is carried out by the RVFAC. Legislation, guidance, etc., is issued by the central office. The establishments can appeal to the central office.

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

The Audit Unit, under ITD, conducts the administrative audit of control and inspection in accordance with the Danish Food Act. The Audit Unit of the ITD of the DVFA carries out risk-based audits, (varies from 2 to 4 annually), in all U.S.-certified establishments.

The Control Coordination Division (CCD) is responsible for: control principles and strategies; general control rules; and food and veterinary controls in general, including the development of tools for the RVFACs to guarantee uniform quality when performing inspections. Overall guidelines of the CCD for the RVFAC control: planning; supervision; guidance on general control issues; case follow-up with reference to inspection performed by the RVFAC; drawing up rules for internal control; coordination of regional laboratories and centrally coordinated laboratory projects; general rules on traceability; publication of inspection results; and collection and processing of data from the control and the RVFAC.

6.2.2 Ultimate Control and Supervision

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

The RVFAC is responsible for recommending the certification or decertification of establishments eligible to export to the U.S. to the DVFA headquarters in Copenhagen. The head of the International Trade Division (ITD) of DVFA 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 U.S.

6.2.3 Assignment of Competent, Qualified Inspectors

The RVFAC is responsible for the initial hiring, training and payment of veterinarians and non-veterinary technicians. Veterinarians receive classroom training in public health and food inspection as part of their normal veterinary degree course of study. Veterinarians receive on-the-job training at the establishment level. Non-veterinary technicians often have experience as a slaughterhouse worker. They are educated at the Danish Meat Trade College. The course consists of 14 weeks of theoretical training and seven weeks of practical training. Ongoing training needs are determined and scheduled by the official veterinarian or the head veterinarian through consultation with the RVFAC. Special emphasis is placed on HACCP, SSOP and supervisory training.

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

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

The Regional Veterinary Supervisors (RVS) 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 and follow-up on issues identified in the previous reports, audit reports, special subjects, legislation and checklists.

- The CCA and the RVFACs have provided several training courses in PR/HACCP systems to increase the level of knowledge of the official inspectors concerning U.S. inspection requirements.

6.2.4 Authority and Responsibility to Enforce the Laws

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

- In three of the 13 establishments audited, SSOP requirements were not fully met; and
- In two of the 13 establishments audited, SPS and EC Directive 64/433 requirements were not fully met.

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. The following deficiency was noted:

- The Regional Veterinary and Food Administration Center (RVFAC) Microbiology Laboratory in Aalborg, which conducts microbiological testing for *Salmonella,* utilized a method differing from the alternative procedures (methods) that have been determined to be equivalent by FSIS. The Danish Veterinary and Food Administration (DVFA) had initially adopted the NMKL method #71 for *Salmonella* testing, but the laboratory started or began using the VIDAS *Salmonella* method # NV 4101-42 without notifying the DVFA. FSIS expects that oversight by the CCA is conducted in a manner to ensure that FSIS alternative-approved testing methods are used.

6.3 Headquarters and Regional Offices Audit

The auditor conducted a review of inspection system documents at the headquarters of the DVFA located in Copenhagen. The auditor also conducted a review of records at the RVFAC located in Ringsted 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 reviewed records 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; and
- Enforcement records, including examples of: criminal prosecution; consumer complaints; recalls; seizure and control of noncompliant product; and withholding, suspending, and/or withdrawing inspection services from or delisting an establishment that is certified to export product to the U.S.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments: 11 were slaughter establishments and two were processing establishments.

- No establishment was delisted by the CCA for failure to meet U.S requirements; and
- No establishment received a Notice of Intent to Delist (NOID).

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 U.S. 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 U.S.-destined product 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 RVFAC Residue Laboratory, located in Aarhus.
    - No deficiencies were noted.

- One RVFAC Microbiology Laboratory, located in Aalborg.
    - The following deficiencies were noted:
        - The Danish Veterinary and Food Administration (DVFA) had initially adopted the NMKL method #71 for *Salmonella* testing but

the laboratory started or began using the VIDAS *Salmonella* method #NV 4101-42 without notifying the DVFA.

The following corrective actions were taken:

- On February 20, 2008, the Head of the International Trade Division (ITD), Danish Veterinary and Food Administration (DVFA), instructed the Microbiology Laboratory in Aalborg not to use VIDAS *Salmonella* method and start using the NMKL method # 71 immediately; and
- The DVFA informed the Director, International Equivalence Staff (IES), Office of International Affairs (OIA), FSIS, of the suspension of the use of VIDAS *Salmonella* method # NV 4101-42 on February 28, 2008.

9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, Denmark's inspection system had controls in place for all aspects of: facility and equipment sanitation; prevention of potential instances of product cross-contamination; good personal hygiene 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 and post-mortem facilities; welfare facilities; and outside premises.

9.1 Sanitation Standard Operating Procedures (SSOP)

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

- In one establishment, an establishment employee failed to follow the dropped meat reconditioning procedures as written in the establishment's SSOP. Numerous contaminated (dropped meat) hams were stacked together (cross-contamination) in a bin and were not handled and reconditioned in a sanitary manner before being added to the edible product in the cut-up room. DVFA officials retained all potentially contaminated product for reconditioning under their supervision;
- In one establishment, condensate from an overhead refrigeration unit and ducts was dripping onto the cleaned/sanitized containers in the equipment washing room;
- In the same establishment, the bottoms of plastic strip curtains were contacting the floor, employees' boots and clean clothes, and cleaned/sanitized edible product containers as they passed through the door from the equipment washing room to the slaughter room;

- In another establishment, condensate was dripping onto tree hooks from the overhead exhaust system and ceilings in the equipment washing room. The hooks had been cleaned and sanitized and were ready to be used for edible product; and
- In the same establishment, an employee was observed handling inedible product and handling edible product in the de-boning room without washing his hands.

9.2 EC Directive 64/433

In two of the 13 establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented. The following deficiencies were noted:

- In one establishment, the packaging supplies were kept in two dry storage rooms in such a manner so as to prevent the inspection of the rooms for the presence of pest or insanitary conditions; for example:

    - The storage racks were not high enough and were stored against the walls or directly on the floor. Accumulation of dirt, cobwebs, and wet flooring were also observed in these rooms. Open spaces at the junctions of walls and ceilings were not sealed to prevent the entry of insects, vermin, and rodents. Cleaning compounds, sanitizing agents, and other chemicals used by the establishment were not stored in a manner to prevent adulteration of packaging materials or insanitary conditions in one of the two dry storage rooms; and

- In one establishment, plastic white containers for edible products were cross-utilized for inedible product in the processing room. Danish Veterinary and Food Administration (DVFA) officials took corrective actions immediately.

Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

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

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

11. SLAUGHTER/PROCESSING CONTROLS

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

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

11.1 Humane Handling and Humane Slaughter

- No deficiencies were observed.

11.2 Hazard Analysis and Critical Control Point (HACCP) Implementation

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

The HACCP programs were reviewed during the on-site audits of the 13 establishments. All 13 establishments had adequately implemented the HACCP requirements.

- No deficiencies were observed.

11.3 Testing for Generic *Escherichia coli* (*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; and
2. Private microbiology laboratories use an AOAC approved NMKL method or AOAC Petrifilm method to analyze samples for generic *E. coli*.

Eleven of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* in lieu of *Enterobacteriaceae* and Total Viable Count and were evaluated according to the criteria employed in the U.S. domestic inspection program. Testing for generic *E. coli* was properly conducted in all 11 of the slaughter establishments.

- No deficiencies were observed.

11.4 Testing for *Listeria monocytogenes*

One of the 13 establishments audited was required to meet the testing requirements for *Listeria monocytogenes* in ready-to-eat (RTE) Product.

- No deficiencies were observed.

11.5 EC Directive 64/433

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

12. RESIDUE CONTROLS

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

The RVFAC Residue Laboratory located in Aarhus was audited. Denmark's National Residue Control Program for 2008 was being followed and was on schedule.

- No deficiencies were observed.

The RVFAC Microbiology Laboratory in Aalborg was audited and following deficiency was observed:

- The Danish Veterinary and Food Administration (DVFA) had initially adopted the NMKL method #71 for *Salmonella* testing, but the laboratory started using the VIDAS *Salmonella* method # NV 4101-42 without notifying the DVFA. However, the following corrective actions were taken:
    - On February 20, 2008, the Head of the International Trade Division (ITD), Danish Veterinary and Food Administration (DVFA), instructed the Microbiology Laboratory in Aalborg not to use VIDAS *Salmonella* method and start using the NMKL method # 71 immediately; and
    - On February 28, 2008, the DVFA informed the Director, International Equivalence Staff (IES), Office of International Affairs (OIA), FSIS, of the suspension of using VIDAS *Salmonella* method # NV 4101-42.

12.1 EC Directive 96/22

- No deficiencies were observed.

12.2 EC Directive 96/23

- No deficiencies were observed.

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

- No deficiencies were observed.

13.2 Testing for *Salmonella* Species

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

1. Establishments take the official *Salmonella* samples and:

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

2. *Salmonella* testing strategy:

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

3. A gauze pad sampling tool is used.

Eleven establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the U.S. domestic inspection program.

Salmonella testing was properly conducted in all 11 slaughter establishments audited.

13.3 Verification Testing Program for Ready-to-Eat (RTE) Product

One of the 13 establishments audited was required to meet the testing requirements for *Listeria monocytogenes* in RTE product.

- No deficiencies were observed.

13.4 Species Verification

Species verification testing was being conducted in all establishments audited.

13.5 Periodic Supervisory Reviews

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

- No deficiencies were observed.

13.6 Inspection System Controls

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

- In three of the 13 establishments audited, SSOP requirements were not adequately enforced; and
- In two of the 13 establishments audited, SPS and EC Directive 64/433 requirements were not adequately enforced.

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 countries 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 March 11 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.

Faizur R. Choudry, DVM
Senior Program Auditor

15. ATTACHMENTS TO THE AUDIT REPORT

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Holstebro, Denmark	02/19-20/08	15	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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

Establishment 15 Danish Crown, Holstebro, Denmark; February19-20, 2008 Slaughter/processing

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

NOTE: All previous audit findings dated April 26-27, 2007 have been corrected

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	/s/ Faizur R. Choudry 3/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Steff-Houlberg Ronne, Denmark	02/6-7/08	22	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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8. Records documenting implementation.	
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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 .	
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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	
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

Establishment 22, Danish Crown, Steff-Houlberg Ronne, Denmark; February 6-7, 2008. Slaughter/Processing

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

NOTE: All previous audit findings dated May 3, 2007, have been corrected.

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz R Choudry 03/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Ringsted, Denmark	1/31& 2/1/08	25	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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

Establishment 25, Danish Crown, Ringsted, Denmark; January 31& February 1, 2008. Slaughter/Processing

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

NOTE: All previous audit findings dated April 19-20, 2007, have been corrected.

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

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 Herning, Denmark	02/25/08	31	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment 31, Danish Crown, Herning, Denmark; February 25, 2008 Slaughter/Processing

45/51/56. Plastic white containers for edible products were cross utilized for inedible product in the processing room. Danish Veterinary and Food Administration (DVFA) officials took corrective actions immediately. [Regulatory references: 9 CFR 416. 3 and 416.17 and C/D 64/433, Annex 1, Chapter III]

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

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
Jutland Meat A/S Struer, Denmark	02/21/08	38	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the 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	
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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*

Establishment 38, Jutland Meat A/S, Struer, Denmark; February 21, 2008. *Slaughter/Processing*

10/51 a). Condensate from an overhead refrigeration unit and ducts was dripping onto the cleaned/sanitized containers in the equipment washing room. [Regulatory references: 9 CFR 416.13 and 416.17]

b. *The bottom of plastic strip curtains* were contacting, floor, employees' boots and clean clothes, and cleaned/sanitized edible product containers, when they were passing through the door of equipment washing to slaughter room. [Regulatory references: 9 CFR 416.13 and 416.17]

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

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	2/26-27/08	53	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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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	
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19. Verification and validation of HACCP plan.	
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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

Establishment 53, Danish Crown, Esbjerg , Denmark; February 26-27, 2008 Slaughter/Processing

10/51. a) Condensate was dripping onto tree hooks from overhead exhaust system and ceilings in the equipment washing room. The hooks had been cleaned and sanitized and were ready to be used for edible product. [Regulatory references: 9 CFR 416.13 and 416.17]

b). An employee was observed handling inedible product and without washing his hands, handling edible product in the de-boning room. [Regulatory references: 9 CFR 416.13 and 416.17]

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

03/17/08

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 Saeby, Denmark	02/12-13/08	71	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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

Establishment 71, Danish Crown, Saeby, Denmark; February 12-13, 2008. Slaughter/Processing

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

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

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 J, Denmark	02/15/08	211	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment 211, Tulip Food Company Svenstrup J, Denmark; February 15, 2008. Slaughter/Processing

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

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Rodding, Denmark	03/04/08	318	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment 318, Danish Crown, Rodding, Denmark; March 4, 2008. Processing

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

NOTE: All previous audit findings dated April 26-27, 2007, have been corrected.

61. NAME OF AUDITOR
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 03/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Vojens, Denmark	03/03/ 08	319	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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

Establishment 319 Danish Crown, Vojens, Denmark; March 3, 2008 Slaughter/processing

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

NOTE: All previous audit findings dated April 25, 2007, have been corrected.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE	
Faizur R. Choudry, DVM	Faizur R. Choudry	3/17/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Horsens, Denmark	03/5-6/08	320	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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.	
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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	
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

Establishment 320, Danish Crown, Horsens, Denmark; March 5-6, 2008. Slaughter/Processing

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

NOTE: All previous audit findings dated April 30, 2007, have been corrected.

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz R Choudry 03/17/08

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	02/18-19/08	338	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	
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

Establishment 338, TiCan a.m.b.a, Thisted, Denmark; February 18-19, 2008. Slaughter/Processing

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

NOTE: All previous audit findings dated April 24, 2007, have been corrected.

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz R Choudry 03/17/08

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
Slagteriet Broerup A/S Brorup, Denmark	2/28/08	801	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment 801, Slagteriet Brorup A/S, Brorup, Denmark; February 28, 2008 Slaughter/Processing

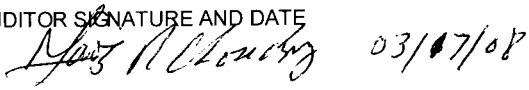
10/51. The establishment employee failed to follow the dropped meat reconditioning procedures as written in the establishment's Sanitation Standard and Operating Procedures (SSOP) such as numerous contaminated (dropped meat) hams were stacked together (cross contamination) in a bin and were not handled and reconditioned in a sanitary manner before being added to the edible product in the cut-up room. DVFA officials retained all contaminated product for reconditioning under their supervision. [Regulatory references: 9 CFR 416.13 (c) and 416.17]

39/51/56. The packaging supplies were kept in two dry storage rooms in a manner that prevented the inspection of dry storage rooms for the presence of pest or insanitary conditions. For example, the storage racks were not high enough and were stored against the walls or directly on the floor. Accumulation of dirt, cobwebs, and wet floor were also observed in these rooms. Open spaces at the junction of walls and ceilings were not sealed to prevent the entry of insects, vermin, and rodents. Cleaning compounds, sanitizing agents, and other chemicals used by the establishment were not stored in a manner to prevent adulteration of packaging materials or creation of insanitary conditions in one of the two dry storage rooms. [9 CFR 416.2(a) (b) and 416.4(c) and EEC C/D 64/433, Annex 1, Chapter II.2 (m)]

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE



Country Response Not Received