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

NOV 24 2009

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 June 23 to July 29, 2009. Comments received from the government of Denmark have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

for Manzoor H. Chaudry

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

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

JUNE 23 THROUGH JULY 29, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Danish Veterinary and Food Administration)
DVFA	Danish Veterinary and Food Administration
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
RVFAC	Regional Veterinary and Food Administration Center
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standard
VEA	European Community/United States Veterinary Equivalence Agreement

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Denmark from June 23 through July 29, 2009. This was a routine audit. Denmark is eligible to export raw and processed pork products to the United States. Between March 11, 2008 and July 29, 2009, Denmark exported more than 120 million pounds of meat products to the United States, of which more than 21 million pounds were reinspected at US ports of entry (POE). A total of 368,154 pounds were rejected at POE, of which no rejections were for food-safety concerns. Activities of the current audit appear in the table below.

The findings of the previous audit during January 29 through March 11, 2008, resulted in no restrictions of any Danish establishment's ability to export pork products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		01/29-03/11, 2008	06/23-07/29, 2009
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	2
	Establishment Level	13	11
Laboratories Audited			
	Microbiology	1	1
	Residue	1	1
Establishments Audited			
	Slaughter/processing	11	7
	Processing	2	4
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	0	1
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	7	23
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	0	19
	Residue Controls	0	0
	Microbiology Controls	1	1
	Inspection/Enforcement Controls	7	29
	Post-mortem Inspection Procedures	0	1

1.3 Summary Comments for the Current Audit

The results of this routine audit, conducted during June 23 through July 29, 2009, resulted in the following actions:

1) No establishments were delisted by the DVFA;
2) One NOID was issued by the DVFA; and

3) FSIS inspection requirements were not fully enforced in nine of the 11 establishments audited. The results of this audit identified an increase in risk area findings in sanitation control (seven establishments), slaughter/processing controls (eight establishments), post-mortem inspection procedures (one establishment), and inspection/enforcement controls (nine establishments).

2. INTRODUCTION

The audit took place in Denmark from June 23 through July 29, 2009.

An opening meeting was held on June 23, 2009, 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).

3. OBJECTIVE OF THE AUDIT

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

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

4. 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 11 establishments: seven swine slaughter and meat processing establishments, and four meat processing establishments. The fourth part involved visits to two government laboratories. One Regional Veterinary and Food Administration Center (RVFAC) laboratory located in Esbjerg that conducts microbiology samples for *Salmonella* testing and another RVFAC laboratory located in Ringsted conducts residue analytical testing of field samples for the national residue testing program were audited.

Program effectiveness determinations of Denmark's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard

Analysis and Critical Control Points (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 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 Food safety and Inspection Service (FSIS) auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

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

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

- A gauze pad sampling tool is used;
- NMKL or AOAC 991.14 method is used to analyze samples;
- Use of an alternate method (TEMPO EC) to detect and quantify generic *E. coli* in raw products; 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, on-going sampling program is used;
- A gauze pad sampling tool is used; and
- NMKL method # 71and iQ Check method are used to analyze samples.

5. 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.).

- 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 (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.

- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stock farming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists.

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:

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

The last two FSIS audits of Denmark were held April 17 through May 11, 2007, and January 29 through March 11, 2008.

The following findings were cited during the 2007 FSIS audit:

- 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 sanitation 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 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, i.e., 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 sanitation SSOP were not adequately described on the records and did not document the corrective actions properly to prevent recurrence of direct product contamination or adulteration;
- Water was splashing from the floor onto the inverted food contact surfaces of the viscera pan conveyor in the slaughter room;

- 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 and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product was not adulterated. For example:
  - Wet loose plastic was observed on the upper panel window through which the clean bins were passing through after washing and sanitizing;
  - An accumulation of fat residue and black grease from the previous day's operation was observed on supports, beams, and the inner side of the plastic protective coverings on both sides of a rail in the swine 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; and
  - 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 pest 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 operation was observed inside of the exhaust system of a washing machine and rusty drying equipment over the containers cleaning line in the washing room; 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 and 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 (CCP) 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 critical limits (CL) 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 the monitoring was implemented effectively;
- In two establishments, the ongoing verification activities were not conducted to ensure that the 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 on- going 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 Regional Veterinary and Food Administration Center (RVFAC) inspection officials and effective supervision of inspection activities at the establishment levels;
- Regional Veterinary Supervisor (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;
- DVAF 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 HACCP/Pathogen Reduction was not sufficient to ensure enforcement of US 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 the FSIS requirements for reviewing the SSOP, daily records, and any corrective

actions taken and direct observation or testing to assess the sanitary conditions in the establishment;

- In three establishments, DVFA inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to prevent recurrence of direct contamination or adulteration in the pre-operational and operational sanitation verification records;
- In seven establishments, DVFA inspection officials were not verifying the adequacy of the HACCP plan(s) at a frequency sufficient to determine that the establishment HACCP plan met the FSIS requirements for reviewing the CCP records, corrective actions, direct observation or measurement at a CCP, onsite observations, and records reviews;
- In one establishment, DVFA inspection officials were not verifying the adequacy of the HACCP plan for the second shift operation;
- In three establishments, DVFA inspection officials did not review and determine the adequacy of corrective actions taken when deviations from a CL occurred; and
- In two establishments, the on-going verification activities were not conducted to ensure that the monitoring was implemented effectively for the 2nd shift operations.

The following findings were cited during the 2008 FSIS audit:

- In three of the 13 establishments audited, SSOP requirements were not fully met. The following deficiencies were noted:
  - In one establishment, and establishment employee failed to follow the dropped meat reconditioning procedures as written in the establishment's SSOP;
  - 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 cloths, and cleaned/sanitized edible product containers as they passed 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.
- In two of the 13 establishments audited, SPS and EC Directive 64/433 requirements were not fully met. 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; and
  - In one establishment, plastic white containers for edible products were cross-utilized for inedible product in the processing room.

7. MAIN FINDINGS

7.1 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.

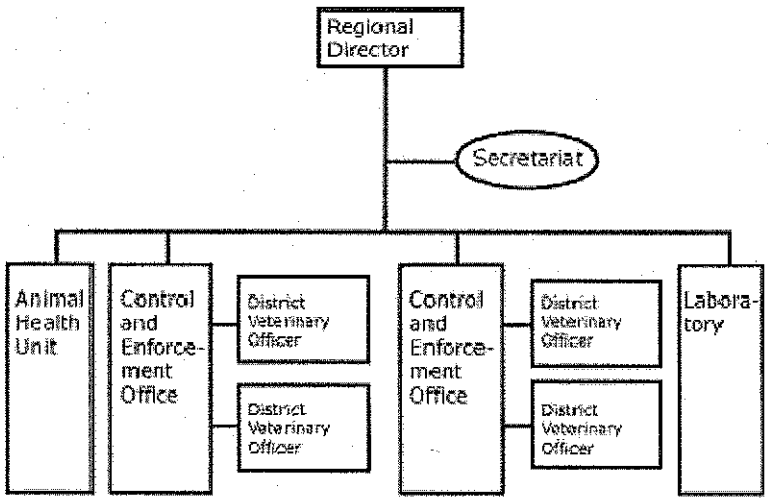
7.2 Government Oversight

7.2.1 CCA Control Systems

The Danish Veterinary and Food Administration (DVFA) is the Central Competent Authority (CCA) under the Ministry of Food, Agriculture, and Fisheries (MFAF).

The DVFA is comparable to the Food Safety and Inspection Service (FSIS) in the United States. Administration, development, coordination, and the formation of rules and regulations take place in the headquarters of the DVFA in Copenhagen. DVFA has approximately 1,860 employees.

Food control and veterinary inspection are handled by three Regional Veterinary and Food Administration Centers (RVFACs). The RVFACs are independent authorities under the DVFA and are in charge of the Veterinary and Food Administration's direct contacts with consumers, enterprises, veterinarians, and livestock owners within each region.



The RVFACs carry out the inspection of food establishments and livestock production and serve as animal health units in the event of outbreaks of contagious diseases among livestock. Each RVFAC is led by a regional director and consists of a veterinary control office, two to four food control offices, a laboratory, and a secretariat.

Three RVFACs are located in the north, south, and east of Denmark and have a total of 10 food control offices.

- DVFA, Region North, with its head office in Århus, has four food control offices in Ålborg, Herning, Viborg and Århus.

- DVFA, Region South, with its head office in Vejle, has four food control offices in Vejle, Esbjerg, Haderslev and Odense.
- DVFA, Region East, with its head office in Ringsted, has two food control offices in Rødovre and Ringsted and a local office in Rønne.

Each RVFAC has a veterinary control office (previously called animal health unit). The primary role of this office is to develop and maintain emergency response to contagious livestock diseases.

The food control offices (previously called control and enforcement offices) are in charge of the inspection process from farm to fork. The inspection of livestock production includes the inspection of animal welfare, veterinary drugs, and animal transport conditions. The reviews of the food establishments include the inspection of internal control programmes, hygiene control, and labelling issues. Meat inspection units also monitor whether food laws are complied with during the slaughter of the animals, the cutting of the meat, and the processing of meat and meat products at slaughter and processing establishments.

7.2.2 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 RVFACs, the DVFA develops and distributes official legislation to the RVFACs. The DVFA coordinates the implementation of inspection activities at each RVFAC and carries out training programs for the regional staff, organizes country-wide campaigns, and assesses the performance of the regional units with regard to food and veterinary control through yearly visits to each unit. The DVFA transposes EC legislation and related FSIS regulations into Danish legislation.

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

The Audit Unit of the International Trade Division of DVFA carries out periodic supervisory reviews of all US certified establishments on the basis of the following minimum frequencies:

- Slaughter establishments: Eight reviews/year
- Processing establishments: Six reviews/year
- Cold storage facilities: Four reviews/year
- ID warehouses: One review/year

7.2.3 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 slaughterhouse workers. 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 emphases are placed on HACCP, SSOP, SPS, and supervision 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; the documentation is 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 CCA and the RVFAC provided several training courses in 2008/2009 in regard to SSOP, SPS, and HACCP to increase the level of knowledge of the official inspectors concerning U.S. inspection requirements.

7.2.4 Authority and Responsibility to Enforce the Laws

The DVFA has the authority for carrying out Denmark's meat inspection program including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. The DVFA not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

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

- In two of the 11 establishments audited, SSOP requirements were not fully met.
- In six of the 11 establishments audited, SPS and EC Directive 64/433 requirements were not fully met.
- In eight of the 11 establishment audited, HACCP requirements were not fully met.

7.2.5 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.

7.3 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 and interviewed inspection officials in the RVFA offices located in Vejle (South Region) and Arhus (North Region) for the purpose of determining the level of government oversight,

supervisory structure, and to review records pertinent to the United States certified establishments. The records review focused primarily on food safety hazards and included the following:

- Government oversight documents, including organizational structure
- Periodic supervisory visits
- Training programs and personnel records of training
- Requirements for employment and payment records of inspection personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Assignment of inspectors, staffing, and inspection coverage of the United States certified establishment
- Inspection records and enforcement actions such as withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States
- Organization of the country's laboratory system
- Microbiology and residue sampling and laboratory analyses
- Export product inspection and control including export certificates
- Sanitation, slaughter and processing inspection procedures and standards
- Control of inedible and condemned materials
- Funding of Denmark's inspection program

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

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 11 establishments: seven were slaughter establishments and four were processing establishments. While no establishments were delisted, one establishment received a notice of intent to delist (NOID) from the CCA. The NOID was issued for deficiencies concerning SSOP and SPS requirements.

Specific deficiencies are noted on the attached individual establishment reports.

9. 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 United States- destined 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 Veterinary and Food Administration Center (RVFAC) Residue Laboratory, located in Ringsted was audited.

- No deficiencies were noted.

One RVFAC Microbiology Laboratory, located in Esbjerg was audited. The following finding was noted;

- Cross-outs were not initialed or dated by the person making the correction.

Both laboratories were ISO certified by DANAK. DANAK is the Danish national body for accreditation appointed by the Danish Safety Technology Authority which is part of the Danish Ministry of Economics and Business Affairs.

10. SANITATION CONTROLS

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

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

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

10.1 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 two establishments, dripping condensate was observed on overhead structures above exposed products/carcasses;
- In one establishment, carcasses with dressing defects (such as fecal contamination) or pathology (such as abscess) on the trim line were in direct contact with each other causing cross contamination; and
- In one establishment, an employee was handling edible products (pork tongues) without washing or sanitizing his hands/knife after touching contaminated tongues with ingesta.

In addition, he was placing all the tongues in a holding container causing direct product contamination.

Specific deficiencies are noted in the attached individual establishment reports.

10.2 Sanitation Performance Standards (SPS)

The Sanitation Performance Standards (SPS) in all audited establishments were found to meet FSIS regulatory requirements with the following exceptions:

- In one establishment, carcasses were contacting non-product contact surfaces in the slaughter floor;
- In one establishment, rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel containers;
- In one establishment, maintenance of over head structures, above exposed product and equipment, had been neglected with build up of rust, plastic wrapping around leaking pipes, holes in walls and ceilings, and broken/cracked plastic covering for electrical cords;
- In another establishment, a number of small holes were observed in the ceiling above exposed products and food contact surfaces;
- In five establishments, beaded condensate was observed on over head structures above exposed products and/or food contact surfaces;
- In one establishment and during pre-operational inspection verification, product residues from the previous day's operation were observed inside of two edible offal chutes; and
- In another establishment and during pre-operational inspection verification the following were observed: 1) product residues and unidentified black color particles from the previous day's operation were observed on several plastic interlock conveyors in a cutting room. 2) Moderate to severe scored cutting boards was observed in a cutting room.

Specific deficiencies are noted in the attached individual establishment reports.

10.3 EC Directive 64/433

In nine of the 11 establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented. For example:

- In two establishments, the temperature of the cutting room, during cutting, was above 12 degrees C.

Specific deficiencies are noted in the attached individual establishment reports.

11. ANIMAL DISEASE CONTROLS

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

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

12. 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.

12.1 Humane Handling and Slaughter

- No deficiencies were observed.

12.2 Hazard Analysis and Critical Control Points (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 audit of 11 establishments. The HACCP plans in these establishments were found to meet basic FSIS regulatory requirements with the following exceptions:

- In five establishments, some of the verification records did not document the results of the ongoing verification;
- In four establishments, verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred;
- In two establishments, HACCP records documenting the monitoring of CCP did not include quantifiable values;
- In two establishments, the HACCP plan only referred to fecal material/ingesta as hazards reasonably likely to occur in the zero tolerance CCP. The hazard analysis did not address milk and there was no supporting documentation or justification why milk was not considered as a food safety hazard that is reasonably likely to occur when slaughtering sows;
- In one establishment, some of the entries on monitoring and verification records were not made at the times when specific events occurred;
- In one establishment, the HACCP plan did not include preventive measures as part of the corrective actions to be followed in response to a deviation from a critical limit; and
- In one establishment, pre-shipment review records were initialed and not signed by the responsible establishment employee.

12.3 Testing for Generic *Escherichia 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 , AOAC Petrifilm method, or alternate method (TEMPO EC) to detect and analyze samples for generic *E. coli.*

Seven of the 11 establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli*. Testing for generic *E. coli* was properly conducted in all seven slaughter establishments.

- No deficiencies were observed.

12.4 Testing for *Listeria monocytogenes*

None of the 11 establishments audited was required to meet the testing requirements for *Listeria monocytogenes* in Ready-To-Eat (RTE) Product.

13. 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 and Food Administration Center Residue Laboratory, located in Ringsted was audited.

- No deficiencies were observed.

Denmark's National Residue Control Program for 2009 was being followed and was on schedule.

13.1 EC Directive 96/22

- No deficiencies were observed.

13.2 EC Directive 96/23

- No deficiencies were observed.

14. 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*.

14.1 Daily Inspection in Establishments

- No deficiencies were observed.

14.2 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 instruction for sample collection and processing;
- Sample verification testing is performed by an official DVFA veterinarian once every week and the sample is analyzed in the 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.

Seven 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 seven slaughter establishments audited.

14.3 Species Verification

Species verification testing was being conducted as required.

14.4 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.

14.5 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 exception:

- In one slaughter establishment, post-mortem inspection procedures were not adequately enforced.
- In two of the 11 establishments audited, SSOP requirements were not adequately enforced.
- In nine of the 11 establishments audited, SPS and EC Directive 64/433 requirements were not adequately enforced.
- In eight of the 11 establishments audited, HACCP 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 counties for further processing.

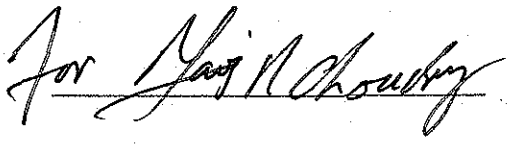
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

A closing meeting was held on July 29, 2009, 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.

Nader Memarian, DVM
Senior Program Auditor



16. 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 Amba Langbro 7, Blans	07/01/2009	14	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Danish Crown Amba, Blans, Est. 14, Slaughter/Processing, 07/01/2009

46/51 56 The following two non-compliances were observed during pre-operational inspection verification:

1) Meat product residues and unidentified black color particles from the previous day's production were observed on several plastic interlock conveyors in the cutting room. The conveyors were ready to use for the day's production of food products. There was no product being processed at the time of the review. [9CFR 416.4, 9CFR 416.17, and Council Directive 64/433/EEC, Annex I]

2) Moderate to severe scored cutting boards were observed in the cutting room. This may create potential for a bio-film formation. There was no product being processed at the time of the review. [9CFR 416.4, 9CFR 416.17, and Council Directive 64/433/EEC, Annex I]

The establishment had written procedures in regard to cleaning of food contact surfaces of facilities, equipment, and utensils. However, the establishment failed to identify the aforementioned non-compliances during its pre-operational monitoring on July 01, 2009. The Danish Inspection rejected all affected areas. The establishment did not start its operation until all non-compliances were corrected and verified by inspection personnel.

22/51 A) The HACCP verification records for review of records component did not document the results of ongoing verification. [9 CFR 417.5(a) (3) and 9CFR 417.8]

B) The HACCP verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred. [9CFR 417.5 (a) 3, 9CFR 417.5 (b), and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

41/56 During operation, beaded condensate was observed on overhead structures in two carcass coolers. Although it was over product, no actual contamination was observed. This was a potential source of carcass contamination during storage or transit of carcasses. [9CFR 416.17, 9CFR 416.2(d), Council Directive 64/433/EEC, Annex I]

The establishment had a written procedure to monitor/control condensation. A review of the daily records, documenting the implementation and monitoring of the sanitation procedures, revealed that the establishment has identified and took corrective actions in regard to condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on July 01, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment will evaluate the effectiveness of its condensation control procedure.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	for

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 Havnevej 8 Struer	07/14/2009	38	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Jutland Meat A/S, Struer, Est. 38, Slaughter/Processing, 07/14/2009

10/56 During operation, dripping condensate was observed on overhead structures above exposed carcasses transferring between slaughter floor and chilling room. [9CFR 416.13 and Council Directive 64/433/EEC]

The establishment had a written procedure to monitor/control condensation. A review of the daily records, documenting the implementation and monitoring of the sanitation procedures, revealed that the establishment has identified and took corrective actions in regard to condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on July 14, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment proposed to evaluate the effectiveness of its condensation control procedure.

22/51 A) The HACCP verification records for review of records component did not document the results of ongoing verification. [9 CFR 417.5(a) (3) and 9CFR 417.8]

B) The HACCP records documenting the monitoring of CCPs did not include quantifiable values. [9CFR 417.5(a) 3 and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

55/56/51 The submaxillary lymph nodes were not incised/examined by the responsible meat inspector. [Council Directive 64/433/EEC of June 26, 1964, Annex 1, Chapter VI 25(b) was not met]

The official veterinarian took immediate corrective actions.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	

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 Amba Gammelby Ringvej 1 Esbjerg	07/16/09	53	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58. Notice of Intent to Delist (NOID)	X
59.	

60. Observation of the Establishment Danish Crown Amba, Esbjerg, Est. 53, Slaughter/Processing, 07/16/2009

10/56 Condensate was dripping from a cooling pipe onto exposed carcasses in a cooler. [9CFR 416.13 and Council Directive 64/433/EEC]
Condensate was wiped out and affected products were retained for proper disposition. The establishment will evaluate the effectiveness of its condensation control procedure.

11/46/51 Carcasses with dressing defects (such as fecal contamination) or pathology (such as abscess) on the trim line were in direct contact with each other causing cross contamination. [9CFR 416.4, 9CFR 416.14, and 9CFR 416.17]
Inspection took immediate control action.

46/51 There were several points on the slaughter floor where carcasses were contacting non-product contact surfaces (such as a saw cabinet wash). This could result in creation of insanitary condition and product adulteration. [9CFR 416.4 and 9CFR 416.17]
The establishment will initiate a plan of action to improve its operational procedures.

11/46
51/56 One establishment employee was responsible for handling/cutting pork tongues which were attached to the rest of the red offals (heart, liver, kidneys, and lungs) in a room next to the slaughter floor. Most of the pork tongues were contaminated with ingesta. This may be a cause of cross contamination between tongues and attached red offals. This employee was observed handling/cutting all pork tongues, including contaminated tongues with ingesta, without washing or sanitizing his hands or knife after touching contaminated tongues. In addition, he was placing all the tongues in a holding container causing an obvious cross contamination. [9CFR 416.4, 9CFR 416.14, 9CFR 416.17, and Council Directive 64/433/EEC]
The presence of insanitary condition/cross contamination was neither detected by the inspection officials nor establishment personnel. The establishment proposed to condemned all affected products and to evaluate the effectiveness of its sanitation procedures.

39/46/51 Maintenance and cleaning of over-product equipment and structures had been neglected to varying degrees in several production areas. Overhead structures throughout the primal cut department were neglected the most with: 1) Rust on pipes and rails, 2) Plastic wrapping around leaking pipes, 3) Numerous holes in walls and ceilings, 4) Broken and cracked plastic covering for electrical cords, and 5) Beaded condensate on ceiling, rails, and cooling units. Although no direct product contamination was observed, the nature and extent of the problems rendered it uncertain that direct product contamination would not occur in this department. [9CFR 416.2, 416.4, 416.17]
Condensation and maintenance problems had been identified in the past by the inspection personnel during daily inspection verification activities and periodic supervisory reviews. It appeared that the inspection enforcement actions were inadequate to correct the non-compliances. The inspection service ordered an improved maintenance and cleaning schedule by the establishment with increased monitoring activities by in-plant inspection during both pre- operational and operational inspection.

41/51/56 Beaded condensate was observed on over head structures above exposed products in a carcass cooler and a ham storage cooler. No direct product contamination was observed. [9CFR 416.2 (d), 9CFR 416.17, and Council Directive 64/433/EEC]
The establishment had a written procedure to monitor/control condensation. A review of the records, documenting the implementation and monitoring of the sanitation procedures, revealed that the establishment has been addressed condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on July 16, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment proposed to evaluate the effectiveness of its condensation control procedure.

45/51 Rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel containers which may prevent the adequate removal of product residue and could become a source of product contamination. [9CFR 416.3 and 9CFR 416.17]
Maintenance issues has been identified in the past by the inspection personnel during daily inspection verification activities and periodic supervisory reviews. The establishment proposed to initiate a plan of action to monitor and fix all containers.

58 The Danish Veterinary and Food Administration (DVFA) issued to the establishment a Notice of Intent to Delist (NOID) for sanitary non-compliances.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	for

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 Amba Wenbovej 11, 9300 Saeby	07/10/2009	71	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Danish Crown Amba, Saeby, Est. 71, Slaughter/Processing, 07/10/2009

The following two non-compliances were observed during pre-operational inspection verification:

45/46 51/56 1) Product residues from the previous day's production were observed inside of two edible offal chutes. These offal chutes were ready to use for the day's production of food products. [9CFR 416.3, 9CFR 416.17, and Council Directive 64/433/EEC, Annex I]

The establishment had written procedures in regard to cleaning of food contact surfaces of facilities, equipment, and utensils. However, the establishment failed to identify the aforementioned non-compliance during its pre-operational monitoring on July 10, 2009. The inspection personnel took regulatory control action and tagged the edible offal room. The establishment cleaned and sanitized the offal chutes prior to start of its operation. The establishment proposed to change the design of edible offal chutes to facilitate its cleaning.

41/56 2) Beaded condensate was observed on over head structures in a cutting room during a pre-operational inspection verification. Even though there was no product in the room, this may cause the creation of insanitary condition. [9CFR 416.2 (d) and Council Directive 64/433/EEC, Annex I]

The establishment had a written procedure to monitor/control condensation. The establishment failed to identify the aforementioned non-compliance during its pre-operational monitoring on July 10, 2009. The establishment wiped out the condensate from the over head structures prior to start of its operation. The establishment will evaluate the effectiveness of its condensation procedure.

15/22/51 The establishment's HACCP plan only referred to fecal material/ingesta as hazards reasonably likely to occur in the zero tolerance CCP. The hazard analysis did not address milk and there was no supporting documentation or justification why milk was not considered as a food safety hazard that is reasonably likely to occur. This establishment slaughters both market hogs and mature swine (sows and boars). [9CFR 310.17 (a); 9CFR 310.18 (a); 9CFR 417.2; 9CFR 417.5; and 9CFR 417.8]

Danish inspection officials did not identify the aforementioned HACCP non-compliance during their review of HACCP plan or CCP records. The establishment will reassess the adequacy of the hazard analysis and its decision making documents. Danish Inspection will issue a new executive order to address fecal material, ingesta, and milk for zero tolerance CCP in all exporting establishments to the US (if applicable).

41/56 During operation, beaded condensate was observed on overhead structures in two carcass coolers. Although it was over product, no actual contamination was observed. This was a potential source of carcass contamination during storage or transit of carcasses. [9CFR 416.2 (d), 9CFR 416.17, and Council Directive 64/433/EEC, Annex I]

The establishment had a written procedure to monitor/control condensation. A review of the daily operational records, documenting the implementation and monitoring of the sanitation procedures, revealed that the establishment has identified and took corrective actions in regard to condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on July 10, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment will evaluate the effectiveness of its condensation procedure.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	For

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
BHJ A/S Protein Foods Ulsnaes 33 Grasten	06/30/2009	868	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	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	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment BHJ A/S Protein Foods, Grasten, Est. 868, Processing, 06/30/2009

22/51 A) The HACCP verification records for review of records component did not document the results of ongoing verification. [9 CFR 417.5(a)(3) and 9CFR 417.8]

B) The HACCP verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred. [9CFR 417.5 (a) 3, 9CFR 417.5 (b), and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

41/56 Heavily beaded condensate was observed on overhead structures above an ascending conveyor belt. Although it was over product, no actual contamination was observed. This was a potential source of product contamination during transit of product. [9CFR 416.17, 9CFR 416.2(d), Council Directive 64/433/EEC, Annex I]

The establishment had a written procedure to monitor/control condensation. A review of the daily records, documenting the implementation and monitoring of the sanitation, revealed that the establishment has identified and took corrective actions in regard to condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on June 30, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment will evaluate the effectiveness of its condensation procedure.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	For

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
Slagtergarden St-Lihme A/S Randbol	07/23/2009	865	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 Slagtergarden St-Lihme A/S, Randbol, Est. 865, Slaughter/Processing, 07/23/2009

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
Nader Memarian. DVM	for

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 Amba Ringsted	07/20/2009	25	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Danish Crown Amba, Ringsted, Est. 25, Slaughter/Processing, 07/20/2009

22/51 A) Some of the entries on HACCP monitoring records were not made at the times when the specific events occurred. [9CFR 417.5(b) and 9CFR 417.8]

B) Some of the entries on HACCP verification records were not made at the times when the specific events occurred. [9CFR 417.5(b) and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

51/56 In two processing rooms, the ambient room temperatures were 12.8 and 13 degrees C. These temperatures were above the prescribed level (12 degree C) as per Council Directive 64/433/EEC.

This non-compliance was not identified either by the establishment's personnel or inspection officials. Danish Inspection officials will verify proposed corrective action(s) and potential product disposition by the establishment. The establishment will provide a plan of action to comply with Council Directive 64/433/EEC.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	For

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 Amba Havnegade 5 Faaborg	06/26/2009	45	Denmark
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT [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	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	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 Danish Crown Amba, Faaborg, Est. 45, Processing, 06/26/2009

22/51 A) The HACCP verification records for review of records component did not document the results of ongoing verification. [9 CFR 417.5(a)(3) and 9CFR 417.8]

B) The HACCP verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred. [9CFR 417.5 (a) 3, 9CFR 417.5 (b), and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

51/56 There was no temperature measuring device in a room that product was being processed and stored. In a measurement by a thermometer, the room temperature was 12.7 degree C which is above prescribed level in Council Directive 64/433/EEC.

This non-compliance was not identified either by the establishment's personnel or inspection officials. Danish inspection officials will verify proposed corrective action(s) and potential product disposition by the establishment. The establishment will provide a plan of action to comply with Council Directive 64/433/EEC.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	for

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 Tulipvej 10. DK-7100 Vejle	06/29/2009	65	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	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	
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	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Tulip Food Company, Vejle, Est.65, Processing (Canning Operation), 06/29/2009

22/51 A) The establishment conducted a pre-shipment review of all records associated with the production of that product including corrective actions, but the records were initialed and not signed by the responsible establishment employee. [9CFR 417.5 9 (c) and 9CFR 417.8]

B) The HACCP verification records did not document the results of ongoing verification. [9 CFR 417.5(a)(3) and 9CFR 417.8]

C) The HACCP records documenting the monitoring of CCPs did not include quantifiable values. Monitoring records had check marks or ok instead of quantifiable values. [9CFR 417.5(a) 3 and 9CFR417.8]

Neither in-plant inspection nor periodic supervisory review records identified these HACCP non-compliances. HACCP record keeping non-compliances were corrected on the day of the review.

39/46 51/56 A number of small holes were observed in the ceiling above exposed products and food contact surfaces in a processing room. Although it was over product, no actual contamination was observed. This may create insanitary conditions and a potential for product contamination. [9CFR 416.2, 9CFR 416.4, 9CFR 416.17, and Council Directive 64/433/EEC]

Records indicated that a number of construction/maintenance issues had been identified by the inspection personnel. The establishment will initiate a plan of action to review its building construction and maintenance.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	

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 Amba, Aabenraavej 11 Skaerbaek	07/03/2009	311	Denmark
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT [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.	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.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Danish Crown Amba, Skaerbaek, Est. 311, Slaughter/Processing, 07/03/2009

15/22/51 The establishment's HACCP plan only referred to fecal material/ingesta as hazards reasonably likely to occur in the zero tolerance CCP. The hazard analysis did not address milk and there was no supporting documentation or justification why milk was not considered as a food safety hazard that is reasonably likely to occur. This establishment slaughters both market hogs and mature swine (sows and boars). [9CFR 310.17 (a); 9CFR 310.18 (a); 9CFR 417.2; 9CFR 417.5; and 9CFR 417.8]

Danish inspection officials did not identify the aforementioned HACCP non-compliance during their review of HACCP plan or CCP records. The establishment will reassess the adequacy of the hazard analysis and its decision making documents. Danish Inspection will issue a new executive order to address fecal material, ingesta, and milk for zero tolerance CCP in all exporting establishments to the US (if applicable).

20/51 The establishment's HACCP plan did not include preventive measures as part of the corrective action to be followed in response to a deviation from a critical limit. [9CFR 417.3 and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified this HACCP non-compliance. HACCP requirement was corrected on the day of the review.

22/51 The HACCP verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred. [9CFR 417.5 (a) 3, 9CFR 417.5 (b), and 9CFR 417.8]

Neither in-plant inspection nor periodic supervisory review records identified this HACCP non-compliance. HACCP record keeping non-compliance was corrected on the day of the review.

41/56 Beaded condensate was observed on overhead structures in a carcass cooler. Although it was over product, no actual contamination was observed. This was a potential source of carcass contamination during storage or transit of carcasses. [9CFR 416.17, 9CFR 416.2(d), Council Directive 64/433/EEC, Annex I]

The establishment had a written procedure to monitor/control condensation. A review of the daily records, documenting the implementation and monitoring of the sanitation, revealed that the establishment has identified and took corrective actions in regard to condensation in the past. However, the establishment failed to identify the aforementioned non-compliance during its operational monitoring on July 03, 2009. Condensate was wiped out and product was retained for proper disposition. The establishment will evaluate the effectiveness of its condensation procedure.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	for Gary N Chowdry

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 Amba Groennegade 21 Fjerritslev	07/13/2009	337	Denmark
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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	
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 Tican Amba, Fjerritslev, Est. 337, Processing, 07/13/2009

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
Nader Memarian. DVM	for Nader M Rhoades

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

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

INTERNATIONAL TRADE DIVISION

att.: James Adams, DVM, Director

10 November 2009
File: 2009-20-7515-00002/HPE

Comments on draft final report of an audit carried out in Denmark covering Denmark's meat inspection system, June 23 to July 29, 2009

Dear James Adams,

The Danish Veterinary and Food Administration (DVFA) acknowledge the receipt of the FSIS's draft final report of an audit carried out in Denmark covering Denmark's meat inspection system, June 23 to July 29, 2009. By letter of September 16, 2009 FSIS has invited DVFA within 60 days of the receipt of the draft report to provide comments regarding the information in the report.
The DVFA would like to state the following comments:

Section 9, Residue and Microbiology Laboratory Audits:

2nd bullet: "Cross-outs were not initialed or dated by the person making the correction"

The DVFA's remark:
The person who makes the registrations at the different steps in an analysis completes a quality control scheme (GLP scheme) in addition to the primary registration schemes. The signature on the GLP scheme covers the primary registration schemes including corrections. If another person than the person who completes the GLP scheme makes corrections in the primary registrations the corrections must be initialed and dated. Thus, if there is a correction in the primary registration schemes, and this correction is not initialed and dated, it means that the person who has signed the GLP scheme is responsible for the corrections. This procedure is accepted by the accreditation body DANAK.

Section 14.5, Inspection System Controls:
3rd bullet: "In nine of the 13 establishments audited, …", should read as follows: " In nine of the 11 establishments audited, …"

Attachments to the report:

Est. No. 71, Danish Crown, Sæby:

Observation 15/22/51, last period: "Danish Inspection will issue a new executive order to address fecal material, ingesta, and milk for zero tolerance CCP in all exporting establishments to the US (if applicable)."

The DVFA's remark: Danish US certified slaughter establishments are required to implement a CCP in their HACCP plan to control contamination of carcasses with fecal material and ingesta, according to Executive Order no. 209 of March 18, 2009.

Furthermore, the DVFA kindly refer to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, Annex III, Section I, Chapter IV, (d):
"removal of the udder must not result in contamination of the carcase with milk or colostrum."

Thus, the DVFA finds that the contamination of carcasses with fecal material, ingesta, and/or milk is adequately addressed in the Danish legislation.

However, in addition to the above, the DVFA intend

- to emphasize to the establishments that contamination of carcasses with milk must be addressed in the establishment's hazard analysis
- to instruct the DVFA inspection personnel to verify compliance with the above requirement laid down in Regulation 853/2004, Annex III, Section I, Chapter IV, (d)
- to instruct the DVFA inspection personnel to perform verification of CCP zero tolerance/milk if the establishment has implemented a CCP zero tolerance/milk in its HACCP plan

Est. 311, Danish Crown, Skærbæk.

Observation 15/22/51, last period: "Danish Inspection will issue a new executive order to address fecal material, ingesta, and milk for zero tolerance CCP in all exporting establishments to the US (if applicable)."
DVFA has the same remarks as above for Est. no. 71.

Please do not hesitate to contact the International Trade Division (3.kontor@fvst.dk) if you have any questions regarding the above comments.

Yours sincerely

Jens Munk Ebbesen
Head of International Trade Division
DVFA